

Exhibit Q

Redacted in its Entirety

Exhibit R

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Exhibit S

Redacted in its Entirety

Exhibit T

**FILE HISTORY FOR US PATENT 4,739,762
(Reexamination No. 90/004,785) (Vol. 2)
JOINTLY SUBMITTED ON BEHALF OF CORDIS
CORPORATION, BSC CORPORATION, SCIMED
LIFE SYSTEMS, INC. AND MEDTRONIC
DATED: April 4, 2000**

**PLAINTIFF'S
EXHIBIT**
13

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)	
)	
Plaintiff,)	
v.)	
)	
ADVANCED CARDIOVASCULAR)	
SYSTEMS, INC., GUIDANT CORPORATION,)	
MEDTRONIC AVE. INC.,)	
BOSTON SCIENTIFIC CORPORATION, and)	
SCIMED LIFE SYSTEMS, INC.,)	
)	
Defendants,)	
)	
and)	
)	Civ. No. 97-550-SLR
ADVANCED CARDIOVASCULAR)	(Consolidated)
SYSTEMS, INC.)	
)	
Counterclaim Plaintiff,)	
)	
v.)	
)	
CORDIS CORPORATION and)	
EXPANDABLE GRAFTS PARTNERSHIP,)	
)	
Counterclaim Defendants,)	
)	
and)	
)	
BOSTON SCIENTIFIC CORPORATION, and)	
SCIMED LIFE SYSTEMS, INC.,)	
)	
Counterclaim Plaintiffs,)	
)	
and)	
)	
MEDTRONIC AVE. INC.,)	
)	
Counterclaim Plaintiff,)	

v.)
)
CORDIS CORPORATION, JOHNSON &)
JOHNSON, and EXPANDABLE GRAFTS)
PARTNERSHIP.)
)
Counterclaim Defendants.)
)
MEDTRONIC AVE, INC.,)
)
Plaintiff.)
v.)
)
CORDIS CORPORATION, JOHNSON &)
JOHNSON, and EXPANDABLE GRAFTS)
PARTNERSHIP.)
)
Defendants.)
)
BOSTON SCIENTIFIC CORPORATION,)
)
Plaintiff,)
v.)
)
ETHICON, INC.; CORDIS CORPORATION;)
and JOHNSON & JOHNSON)
INTERVENTIONAL SYSTEMS CO.,)
)
Defendants.)
)

C.A. No. 97-700-SLR

Civil Action No. 98-19-SLR

FILE HISTORY FOR U.S. PATENT 4,739,762
(Reexamination No. 90/004,785) (Vol. 2)
JOINTLY SUBMITTED ON BEHALF OF CORDIS CORPORATION,
BOSTON SCIENTIFIC CORPORATION,
SCIMED LIFE SYSTEMS, INC. AND MEDTRONIC AVE, INC.

Dated: April 4, 2000

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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PATENT NUMBER: _____ FILING DATE: _____ PATENT UNDER REEXAMINATION: _____ ATTORNEY DOCKET NO.: _____

EXAMINER: _____

ART UNIT: _____ PAPER NUMBER: _____

DATE MAILED: 06/01/98

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WASHINGTON, D.C. 20231

OFFICE ACTION IN REEXAMINATION

☒ Responsive to the communication(s) filed on 1-12-98 2-18-98
1-20-98 4-9-98 ☐ This action is made FINAL.

A shortened statutory period for response to this action is set to expire 740 month(s) from the date of this letter. Failure to respond within the period for response will cause termination of the proceeding and issuance of a reexamination certificate in accordance with this action. 37 CFR 1.550(d). EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(e).

PART I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Information Disclosure Citation, PTO-1449.
3. ☐ Notice of Informal Patent Drawing, PTO-948.
4. ☐ _____

PART II SUMMARY OF ACTION:

- 1a. ☒ Claims 1-43 are subject to reexamination.
- 1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been cancelled.
3. ☒ Claims 17, 32 are confirmed.
4. ☐ Claims _____ are patentable.
5. ☒ Claims 1-16, 18-31, 33-43 are rejected.
6. ☐ Claims _____ are objected to.
7. ☐ The formal drawings filed on _____ are acceptable.
8. ☐ The drawing correction request filed on _____ is ☐ approved, ☐ disapproved.
9. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received, ☐ not been received, ☐ been filed in Serial No. _____ filed on _____.
10. ☐ Since the proceeding appears to be in condition for issuance of a reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 435 O.G. 213.
11. ☐ Other _____

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It would have been obvious to locate the fixation sleeve either to the inside or the outside of the Kononov prosthesis in the same manner set forth in the combination of Lazarus and Ersek above and for substantially the same reasons. The Kononov prosthesis is wrapped in a spiral around the catheter and is uncoiled as it expands in diameter during balloon inflation. Since the prosthesis is in the form of a spiral, any suturing of the fixation sleeve to the prosthesis would naturally be limited to an arc which is slightly less than 360 degrees around the circumference of the prosthesis to allow the prosthesis to uncoil.

Tubular sheath 1 of Kononov would shield the inner wall of the body passageway from the narrow outwardly projecting edges of the fixation sleeve in substantially the same way that the guide 18 of Lazarus would perform this function as explained above. Since staples are located on each end of the Kononov prosthesis, it would have been obvious to use a fixation sleeve at each end.

As to claims 35-38, Kononov shows a first retainer ring member 1 and a second retainer ring member (the distal portion of tube 2 which is within the ring member 1) which would confine the prosthesis (the Ersek fixation sleeve) between them and thus mount and retain the prosthesis.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kononov in view of Ersek as applied to claim 1 above, and further in view of either Fischell et al. (4,768,507) or

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Bokros et al. (3,526,005). Including a biologically inert coating on the Ersek fixation sleeve in order to provide decreased thrombogenicity of the sleeve would have been obvious for the reasons set forth above.

Claims 39, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kononov in view of Ersek as applied to claims 1, 35 and 37 above, and further in view of Bokros et al. (3,526,005). Using tantalum as the material for the Ersek fixation sleeve in order to provide good compatibility with the body would have been obvious for the reasons set forth above.

Claims 13-16, 18, 23, 24, 29-31, 33 and 34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ersek (3,657,744). Ersek shows an expandable graft or prosthesis 16 which meets all of the structural limitations in the claims. The Ersek fixation sleeve 16 is a graft or prosthesis since it is implanted within a blood vessel. Alternatively, it would have been obvious that the Ersek fixation sleeve 16 is a graft or prosthesis since it is implanted within a blood vessel. The Ersek member 16 is an "intraluminal" member and has a first diameter "which permits intraluminal delivery" as required by claims 13 and 24 for the following reasons. First, the Ersek member 16 of figure 1 is delivered into the lumen of the aorta 11 and arteries 13, 14 as seen in this figure while the Ersek member 16 of figure 8 is delivered into the lumen of the aorta as

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described in col. 4, lines 41-46. Second, assuming arguendo that the delivery of the Ersek member 16 is not considered to be "intraluminal" because the member is not delivered to its desired location in the artery from a distant insertion site, the Ersek member, without modification, is capable of being so delivered by percutaneous insertion into the artery by appropriate instrumentation. Since the apparatus rather than the method of delivering the apparatus is claimed, the Ersek member meets all of the limitations in these claims. As to claims 23 and 34, the outside of the wall surface of the Ersek tubular member 16 is "smooth". Although the Ersek members 22 which form the wall are twisted to the configuration shown in figure 5 such that the outside of the wall surface is, for the most part, narrow edges rather than the wider surfaces of the ribbon-like members 22, each of these narrow edges is smooth. As one follows the narrow outwardly directed edges, no abrupt obstacle is met. The affidavit of Erik K. Antonsson, Ph.D., P.E., C35148-84 (Appendix VIII, Exhibit G) (Ersek Notebook) which was cited on sheet 17 of 20 in the information disclosure statement filed April 9, 1998 has accompanying photographs of an "Ersek style stent". These photographs show the outside surface of the sleeve has having gentle undulations rather than abrupt obstacles in it. The areas where the ribbon-like members curve and twist (at the intersection of the members) appear to be gently (or smoothly) curved and

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twisted and do not include an abrupt obstacle. Ultimately, whether or not an object is considered to be smooth is largely subjective. Smoothness is relative. No surface is perfectly "smooth".

Claims 19-22 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek (3,657,744) in view of either Fischell et al. (4,768,507) or Bokros et al. (3,526,005). Including a biologically inert coating on the Ersek fixation sleeve in order to provide decreased thrombogenicity of the sleeve would have been obvious for the reasons set forth above.

Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek in view of Bokros et al. (3,526,005). Using tantalum as the material for the Ersek fixation sleeve in order to provide good compatibility with the body would have been obvious for the reasons set forth above.

Claims 1-3 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kononov (U.S.S.R. 660,689) in view of Kornberg (4,617,932) and Lazarus (4,787,899). Initially, it is noted that Kononov indicates that prosthesis 3 is placed on the inflatable balloons with each end opposite a balloon. Then, the prosthesis is coiled into a spiral around elastic tube 5. (col. 2, lines 14-20) The term "spiral" is broad enough to include two possibilities. The first possibility is that the prosthesis is wrapped around tube 5 in a manner similar to the way a grip is wrapped on a tennis racquet. That is, the edge of the grip forms

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a helix and each winding of the grip partially overlaps the previous winding. The second possibility is that the prosthesis is wrapped around tube 5 in a manner similar to the way the prosthesis in Beck et al. (U. S. Patent No. 4,877,030) is wrapped (or coiled) around the balloon. (This patent is not being applied as a reference but is merely cited for purposes of illustration.) That is, the rectangular sheet of prosthesis is rolled (or coiled) into a tube while keeping its edges aligned so that an end view or a cross-sectional view reveals the shape of a spiral. One of ordinary skill in the art would believe that the second meaning of "spiral" either definitely or probably applies to the Kononov prosthesis for the following reasons. First, no helical or diagonal lines within prosthesis 3 to indicate a helical edge of the prosthesis are seen in the figure. Second, Kononov indicates that prosthesis 3 is placed on the inflatable balloons with each end opposite a balloon prior to wrapping it. One could not keep both ends of the prosthesis fixed while wrapping the prosthesis to form of a single helix. Therefore the Kononov prosthesis will be considered to be wrapped according to the second meaning of "spiral" in this rejection.

Kononov substantially discloses the claimed method. However, Kononov fails to show a plurality of slots in the tubular prosthesis. Kornberg teaches that a tubular prosthesis for the intraluminal repair and treatment of aortic aneurysms should

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#17/A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reexamination Control No. 90/004,785)
)
Filed: October 6, 1997) Group Art Unit: 3731
)
In Re U.S. Patent No. 4,739,762) Primary Examiner:
) Michael Thaler
Issued: April 26, 1988)
)
Inventor: Julio C. Palmaz)

AMENDMENT

Responsive to the Office Action mailed June 1, 1998, please amend the above-identified application as follows.

In The Claims:

1. (Amended) A method for implanting a prosthesis within a body passageway comprising the steps of:

utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the prosthesis upon a catheter;

inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and

expanding and deforming the prosthesis at [a desired] the location of an obstruction ^{existing natural} within the body passageway by expanding a portion of the catheter associated with the

prosthesis to force the prosthesis radially outwardly into contact with the body passageway,
the prosthesis being deformed beyond its elastic limit.

13. (Amended) An expandable intraluminal vascular graft, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen and wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

Please cancel claim 23.

24. (Amended) An expandable prosthesis for a body passageway, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform

thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member,

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen and wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

Please cancel claim 34.

35. (Amended) An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable and deformable, thin-walled tubular prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis, the prosthesis having a first diameter which permits intraluminal delivery of the prosthesis into a body passageway having a lumen and wherein the outside of the wall surface of the prosthesis is a smooth surface when the prosthesis has the first diameter; and

2. Ersek U.S. Patent No. 3,657,744 - In contrast to the minimally invasive procedure of Dr. Palmaz, the Ersek patent teaches a method of implanting a prosthesis in a living body during an open surgical procedure.

The Ersek patent teaches the use of an expandable sleeve fixation device 16 to secure a vessel graft or a heart valve into the body. The theory of the Ersek patent is to provide a rapid fixation technique, which supposedly obviates the need to suture the prosthetic member into the body. Ersek teaches a complex surgical procedure wherein one or more fixation sleeves is or are secured to the prosthesis to be implanted, the abdominal or chest cavity is opened, the diseased portion of the body is removed, body passageways are clamped, and the fixation sleeves are forced into place, where expansion of the sleeve or sleeves is then done. There is no teaching within the Ersek patent that the sleeve 16 may be utilized to *treat* an obstructed body passageway. The sole and only teaching within the Ersek patent regarding utilization of sleeve 16 is as a *fixation device* in substitution for sutures. To aid in fixation and to resist forces tending to pull out the implanted prosthetic device, the Ersek sleeve has outwardly projecting sharp metal edges.

As is clear from the last paragraph of column 2, and the first paragraph of column 3 of the Ersek patent, the fixation sleeve 16 is formed of expanded metal. The configuration of expanded metal is well-known, and is accurately illustrated in Figure 5 of Ersek. As is evident from the Ersek specification (Column 2, lines 56-75 through Column 3, lines 1-9) sleeve 16 has the first diameter configuration of Figure 5 prior to further expansion by expander tool 18. A sample of conventional expanded metal was shown to Examiner Thaler

at the July 8th interview, and that sample is accurately depicted in its first diameter configuration in Exhibit 1 hereto. As shown therein and in Ersek Figure 5, in the first diameter configuration, the wall of sleeve 16 is of varying thickness because the strands of the sleeve have twisted out of the plane of the starting material. Moreover, the bonds or bridges at the junctions of the strands protrude inwardly and outwardly of the plane of the starting material, and as a result the Ersek sleeve 16 has a non-uniform wall of varying thickness.

Since the bonds or bridges extend generally radially outwardly of the sleeve 16, the sleeve has 100% variance in thickness as compared to the thickness of the starting material in the areas of the bonds or bridges. The strands of the Ersek fixation sleeve are inclined with respect to the plane of the starting material. The strands have an inwardly projecting inner edge that is spaced inwardly of the plane of the starting material by the width of the strand at one end thereof and disposed in the plane of the starting material at the opposite end thereof. The strands have an outwardly projecting edge that is disposed in the plane of the starting material at one end thereof and which is spaced outwardly from the plane of the starting material by the width of the strand at the opposite end thereof. The sleeve 16 has a plurality of outwardly projecting edges which, Ersek teaches, embed themselves into the vessel wall to hold the sleeve 16 and its associated graft in place. The inner and outer surfaces of the Ersek sleeve 16 are not smooth, as that term is understood by persons of skill in the art (Andros Declaration, paragraphs 18 and 21). See also dictionary definitions of smooth - "having an even or level surface; having no roughness or projections that can be seen or felt", and rough

- "not smooth or level; having bumps, projections, etc." (Exhibit 2 hereto) from which it is clear that such terms are commonly understood antonyms, and mutually exclusive of one another. Because the Ersek sleeve 16 does not have a smooth outer surface, it can not be intraluminally delivered, as that term is understood by persons of skill in the art (Andros Declaration, paragraphs 16 and 21).

Furthermore, there is no teaching in the Ersek patent that the fixation sleeve 16 may have a "variable" second diameter; instead, the Ersek sleeve 16 has a first diameter as mounted on the expander tool 18 and a second fixed diameter which results from actuation of the expander tool 18 (Andros Declaration, paragraph 22). Still further, there is no express teaching within the Ersek patent that the expander tool 18 also expands the lumen of the body passageway; all that is taught is that the tool expands the sleeve 16 sufficiently to embed the outwardly projecting edges thereon into the wall of the vessel (Andros Declaration, paragraph 22).

The deficiencies of the Ersek patent are recognized by others. For example, in the Antonsson Affidavit referred to on page 14 of the Action dated June 1, 1998, which includes photographic exhibits of a model (also shown to, and discussed in detail with, Examiner Thaler at the above-mentioned interviews) of an "Ersek-style" fixation sleeve submitted to the Patent and Trademark Office in connection with a reexamination of Palmaz U.S. Patent No. 4,733,665, it is concluded in paragraph 9 that the outer wall surface of the Ersek fixation sleeve is not smooth, not even substantially smooth. In paragraph 10 of the Antonsson Affidavit, it is stated that the wall thickness "varied at different points" and "ranged from a

minimum thickness of 0.0035 inches to a maximum thickness of 0.0045 inches." While the photographs appended to the Antonsson Affidavit illustrate a model of an Ersek sleeve in an expanded configuration (expanded on a mandrel and not by a balloon), the second diameter or expanded configuration is substantially the same as the first diameter unexpanded configuration, i.e., the wall is of variable, and not substantially the same, thickness in both configurations, and the wall surface is rough, in both configurations. It should be borne in mind that Professor Antonsson was a retained expert by Cook, Inc., the accused infringer, in litigation instituted by Johnson & Johnson Interventional Systems, Co. (JJIS), and was a witness whose interests are adverse to those of Dr. Palmaz.

Similarly, Advanced Cardiovascular Systems, Inc. (ACS), a major competitor of Dr. Palmaz's* licensee, JJIS and its successor Cordis Corporation, acknowledged that Ersek does not have a smooth surface.

Appended hereto as Exhibit 3 is a copy of Lau et al. U.S. Patent No. 5,514,154, assigned to ACS, as well as a copy of an Amendment filed in response to an Office Action dated January 31, 1995 in the application for the '154 patent. ACS was successful in obtaining their patent by distinguishing their product as having a smooth outer wall surface prior to expansion, in contrast to Ersek, which had projections on its outer wall surface prior to expansion. At the bottom of page 5 of the enclosed Amendment, ACS stated that "the

* The '762 Palmaz patent is owned by Expandible Grafts Partnership (EGP) and exclusively licensed to JJIS and its successor, Cordis.

3. Claims 13-34, 40 and 41 Are Not Anticipated By, Or Obvious From, Ersek

Independent claims 13 and 24, particularly as amended herewith to include the subject matter of original claims 23 and 34, contain meaningful structural recitations that are not present in, or suggested by, Ersek.

Ersek does not disclose a "thin-walled" tubular member. The Ersek fixation sleeve has a thickness at the bridge or bond areas that is several times the thickness of the starting material.

The wall of the Ersek sleeve, to the extent that it exists, is comprised of twisted, inclined strands, which present inwardly and outwardly projecting edges and bridge portions that extend radially outwardly of the sleeve. This configuration does not provide "a surface", that is "disposed between the first and second ends" of a tubular member as is recited in claims 13 and 24.

As is evident from the specification of the '762 patent, with particular reference to Figure 1A, the connecting members and elongate members that collectively form the tubular member 71 have an outer surface that is disposed in a common cylindrical plane. No comparable wall surface is present in Ersek's fixation sleeve, and it would render Ersek inoperable for its intended purpose to modify sleeve 16 and eliminate the outwardly projecting edges, since the thus modified sleeve would eliminate the very structure contemplated by Ersek for retaining the associated graft or heart valve within the body passageway.

Clearly, the Ersek sleeve cannot be fairly said to have a wall surface with "a substantially uniform thickness". The expanded metal Ersek sleeve has bridge portions that are several times as thick as the strands. The bridge areas extend generally radially outwardly of the sleeve 16. The strands extending between the bridge portions are twisted to have inwardly and outwardly projecting edges. This irregular and variable configuration is rough and is the antithesis of "substantially uniform thickness". The use of the term "substantially uniform" does not exclude some variations in dimension between the inner and outer surfaces of the wall. Even so, it is clear that Ersek's rough and irregular wall does not have substantially uniform thickness. Antonsson Affidavit, paragraph 10.

Independent claims 13 and 24 also distinguish over Ersek in the recitation of "the tubular member having a first diameter which permits intraluminal delivery". Intraluminal delivery in the context of the Palmaz patent is a term which has a well-understood meaning, i.e., delivery through the lumen of a body passageway from a remote location to the desired location without surgically exposing the desired location of the body passageway. (Andros Declaration, paragraph 16; Column 1, lines 30-37 of '762 patent.) Merely placing one end of an Ersek fixation sleeve into a surgically exposed open end of a body passageway, e.g., iliac arteries 13 and 14, is not intraluminal delivery as that expression is used in claims 13 and 24. Those skilled in the art would not even consider intraluminally delivering the expanded metal sleeve of Ersek through the vasculature of a lumen, since the sharp metal outwardly projecting edges thereon would present a clear risk to the patient (Andros Declaration, paragraph 21). Certainly, the rigid expander tool 18 of Ersek would be incapable of

intraluminally delivering sleeve 16. (Andros Declaration, paragraph 21.) Moreover, there is no reason to use a suture substitute (Ersek's fixation sleeve) in a site or location where no suturing takes place (site or location where Palmaz stent is implanted).

While the Ersek fixation sleeve 16 may have a second expanded size, such second size is fixed by the predetermined stroke of rod 33 and is not variable and dependent, as expressly set forth in the claims. As is clear from lines 15 and 16 of column 3 of Ersek, different size sleeves are chosen for the implant being made. Thus, there is also no teaching or suggestion in Ersek that sleeve 16 has a second expanded diameter which is "variable and dependent upon the amount of force applied to the tubular member," as is set forth in independent claims 13 and 24. The ability to have effective control over the final expanded diameter is an important aspect of the invention of the '762 patent.

Moreover, it is questionable whether or not the Ersek sleeve has "a" second diameter. It should be noted that when the sleeve 16 is expanded, the force applied by rings 35 are at spaced locations adjacent the ends of the sleeve. No outwardly directed force is applied to the mid-portion of the sleeve, and while no Ersek device is available for evaluation, it appears that the mid-portion of the sleeve would have a lesser diameter than the ends thereof. With that configuration, only end portions of the sleeve will be forced into intimate contact with the interior of the vessel passageway, forming at best seals of marginal integrity that clearly would be susceptible to leakage.

Also, there is no express teaching in Ersek that expansion of sleeve 16 expands the lumen of the body passageway. Examination of the iliac artery 13 in Figure 1 does not show

it expanded. Even if it can be argued that the expander tool 18 would inherently function to expand the lumen, such expansion would be incidental and not recognized by those skilled in the art as a teaching of expanding the lumen.

Lastly, independent claims 13 and 24 have been amended to include the subject matter of dependent claims 23 and 34, respectively. No change of substance has been made regarding claims 23 and 34, and such claims with identical scope have merely been rewritten in independent form. There is no question but that Ersek completely fails to disclose a tubular member wherein the outside of the wall surface is a smooth surface, when the tubular member has the first diameter. It is important to remember that "smooth" characterizes the outside of the wall surface that is defined as disposed between the first and second ends of the tubular member. No portion of the outward surface of the Ersek sleeve is "smooth", as that term is understood by those of skill in the art, and certainly no relatively smooth portion of the outside surface of Ersek extends from end-to-end of the sleeve.

Claims 14-22, which depend from claim 13, and claims 25-33, which depend from claim 24, are allowable for all of the reasons advanced above, and for the further reason that each claim sets forth further features of the '762 invention.

With respect to claims 40 and 41, Bokros adds nothing to cure the basic deficiencies of Ersek, and thus claims 40 and 41 are believed to be patentable for the reasons set forth above regarding claims 13 and 24 and for the further reason that claims 40 and 41 each further characterize the graft and prosthesis defined in their parent claims.

Thus, there is absolutely no teaching or suggestion of the invention set forth in claims 13 and 24 in Ersek and the Examiner's interpretation of Ersek may seem obvious only by applying hindsight following the teachings of Dr. Palmaz. This is improper. See, for example, *W. L. Gore Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 312, 313 (Fed. Cir. 1983), where it was stated:

To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

It is difficult but necessary that the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art. Had that been here done the inventions set forth in claims 3 and 19 of the '566 patent could only have been held non-obvious to those skilled in the art at the time those claimed inventions were made.

4. Lazarus U.S. Patent No. 4,787,899 and Kononov U.S.S.R. 660,689

The Examiner has treated the teachings of Lazarus and Kononov as equivalent to one another in applying the references to the claims, and applicant does not disagree that these references can be considered to disclose somewhat similar devices, systems and methods. Because the description in the Lazarus patent is somewhat more complete, applicants' remarks will be primarily directed to this reference, although most such remarks have equal applicability to Kononov.

Exhibit U

FILE HISTORY FOR US PATENT 4,739,762
(Reexamination No. 90/004,785) (Vol. 3)
JOINTLY SUBMITTED ON BEHALF OF CORDIS
CORPORATION, BSC CORPORATION, SCIMED
LIFE SYSTEMS, INC. AND MEDTRONIC
DATED: April 4, 2000

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)	
)	
Plaintiff,)	
v.)	
)	
ADVANCED CARDIOVASCULAR)	
SYSTEMS, INC., GUIDANT CORPORATION,)	
MEDTRONIC AVE, INC.,)	
BOSTON SCIENTIFIC CORPORATION, and)	
SCIMED LIFE SYSTEMS, INC.,)	
)	
Defendants,)	
)	
and)	Civ. No. 97-550-SLR
)	(Consolidated)
ADVANCED CARDIOVASCULAR)	
SYSTEMS, INC.)	
)	
Counterclaim Plaintiff,)	
)	
v.)	
)	
CORDIS CORPORATION and)	
EXPANDABLE GRAFTS PARTNERSHIP.)	
)	
Counterclaim Defendants,)	
)	
and)	
)	
BOSTON SCIENTIFIC CORPORATION, and)	
SCIMED LIFE SYSTEMS, INC.,)	
)	
Counterclaim Plaintiffs,)	
)	
and)	
)	
MEDTRONIC AVE, INC.,)	
)	
Counterclaim Plaintiff,)	

v.)
)
CORDIS CORPORATION, JOHNSON &)
JOHNSON, and EXPANDABLE GRAFTS)
PARTNERSHIP.)
)
Counterclaim Defendants.)
_____)
MEDTRONIC AVE. INC.,)
)
Plaintiff.)
v.)
)
CORDIS CORPORATION, JOHNSON &)
JOHNSON, and EXPANDABLE GRAFTS)
PARTNERSHIP.)
)
Defendants.)
_____)
BOSTON SCIENTIFIC CORPORATION,)
)
Plaintiff.)
v.)
)
ETHICON, INC.; CORDIS CORPORATION;)
and JOHNSON & JOHNSON)
INTERVENTIONAL SYSTEMS CO.,)
)
Defendants.)
_____)

C.A. No. 97-700-SLR

Civil Action No. 98-19-SLR

FILE HISTORY FOR U.S. PATENT 4,739,762
(Reexamination No. 90/004,785) (Vol. 3)
JOINTLY SUBMITTED ON BEHALF OF CORDIS CORPORATION,
BOSTON SCIENTIFIC CORPORATION,
SCIMED LIFE SYSTEMS, INC. AND MEDTRONIC AVE. INC.

Dated: April 4, 2000

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NY01 269775 v 1

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#20 / D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reexam Control No. 90/004,785)
)
Filed: October 6, 1997) Art Unit 3731
)
For: U.S. Patent No. 4,739,762) Examiner M. Thaler
)
Inventor: Julio C. Palmaz)

GROUP 330

AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please rescind the previous cancellation of claims 23 and 34 so that the
patentability of these claims may now be confirmed.

Please cancel claims 13 and 24.

Please amend claims 14, 16, 17, 18, 19, 25, 29, 31, 32 and 33 as follows:

14. (Amended) The expandable intraluminal vascular graft of claim [13]

D1 23. wherein the slots are uniformly and circumferentially spaced from adjacent slots and the
slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular
member, whereby at least one elongate member is formed between adjacent slots.

16. (Amended) The expandable intraluminal vascular graft of claim [13]

D2 23. wherein the tubular member does not exert any outward, radial force while the tubular
member has the first or second, expanded diameter.

17. (Amended) The expandable intraluminal vascular graft of claim [13] 23, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

18. (Amended) The expandable intraluminal vascular graft of claim [13] 23, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

19. (Amended) The expandable intraluminal vascular graft of claim [13] 23, wherein the tubular member has a biologically inert coating on the wall surface.

20. (Amended) The expandable prosthesis for a body passageway of claim [24] 34, wherein the tubular member has a biological inert coating on the wall surface.

21. (Amended) The expandable prosthesis of claim [24] 34, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

22. (Amended) The expandable prosthesis of claim [24] 34, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second expanded diameter.

23. (Amended) The expandable prosthesis of claim [24] 34, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter, and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

25 33. (Amended) The expandable prosthesis of claim [24] 34, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

REMARKS


This Amendment is being made to comply with a specific request made during a telephone discussion initiated by Examiner Thaler to the undersigned on August 20, 1998.

The purpose of this Amendment is to present claims 23 and 34 in a manner so that their patentability can be confirmed. Claims 14, 16, 17, 18, 19, 25, 29, 31, 32 and 33 have been amended so that they now depend from a patentable claim 23 or 34.

Applicant respectfully requests the issuance of a Notice of Intent to Issue a Reexamination Certificate with respect to this reexamination proceeding.

Respectfully submitted,

Date: August 21, 1998


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PWRAP 003245

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CERTIFICATE OF DELIVERY

I hereby certify that this paper is being hand-delivered to the U.S. Patent and
Trademark Office on August 24, 1998.

Samchai Chingam

2008-24, 17:11:39
GROUP 350

PWRAP 003246

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EXAMINER'S AMENDMENT

Authorization for this examiner's amendment was given in a telephone interview with Mr. Milnamow on August 24, 1998.

Claims 40 and 41 have been amended as follows:

4040. (Amended) The expandable intraluminal vascular graft of claim [13] 23, wherein tantalum is utilized for the tubular member.

4141. (Amended) The expandable prosthesis of claim [24] 34, wherein tantalum is utilized for the tubular member.

REMARKS

Claims 40 and 41 have been amended so that they now depend from a confirmed claim 23 or 34.

REASONS FOR ALLOWANCE

Claim 1

Claim 1, as amended, includes the step of expanding and deforming the prosthesis at the location of an existing natural obstruction within the body passageway. Initially, it should be noted that the examiner considers the word "existing" in this phrase to require that the natural obstruction exist while the step of expanding and deforming the prosthesis is occurring. However, the limitation is considered by the examiner to be broad enough to include the possibility that the existing natural obstruction is one which has been reduced in size by balloon angioplasty or other methods.

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Claim 1, prior to the amendment, was rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus (4,787,899) in view of Ersek (3,657,744). This rejection is no longer considered to be proper. Even if an Ersek type of fixation sleeve were placed on the Lazarus graft, it would not have been obvious to locate this assembly within the body passageway at the location of an existing natural obstruction since the placement of the assembly at the obstruction would only further reduce the diameter of the lumen by adding at least one additional layer to the obstruction. Such a result would clearly be undesirable since the fluid flow through the body passageway would be reduced. Even if an Ersek type of fixation sleeve were placed on the Lazarus graft, an artisan following the teachings of Lazarus and Ersek would not have found it to be obvious to expand the body lumen at a natural obstruction by expanding the Ersek fixation sleeve to compress the natural obstruction since there is no teaching in Ersek of using the fixation sleeve to expand the body lumen and there is no teaching in Lazarus of using the graft to expand the body lumen. In addition, the supplemental declaration of George Andos, M.D. under 37 C.F.R. 1.132 indicates on paragraph 3 therein, that it was not known, nor would it have been obvious, to locate a flexible Lazarus DACRON graft in an obstructed, or stenosed, location of a blood vessel.

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Claim 1, prior to the amendment, was also rejected under 35 U.S.C. 103(a) as being unpatentable over Kononov (U.S.S.R. 660,689) in view of Ersek (3,657,744). The Kononov (U.S.S.R. 660,689) device is similar in many respects to that disclosed in Lazarus. This rejection is no longer considered to be proper for substantially the same reasons as those given above.

Claim 1, prior to the amendment, was also rejected under 35 U.S.C. 103(a) as being unpatentable over Kononov (U.S.S.R. 660,689) in view of Kornberg (4,617,932) and Lazarus (4,787,899). This rejection is no longer considered to be proper for substantially the same reasons as those given above. Even if slots were incorporated into the Kononov prosthesis in view of Kornberg and even if the Kononov staples were formed by deforming them beyond their elastic limit in view of Lazarus, it would not have been obvious to locate this assembly within the body passageway at the location of an existing natural obstruction for the reasons given above.

Claim 44

Claim 44 is a new claim. This claim includes the step of expanding and deforming the stent prosthesis at an area of stenosis within the coronary artery. This claim is more limited than amended claim 1. It would not have been obvious to locate either the Lazarus or the Kononov device within the coronary artery at the

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area of stenosis for substantially the same reasons as those given above.

Claims 23 and 34

Claims 23 and 34 have not been amended. These claims were rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Ersek (3,657,744). This rejection is no longer considered to be proper. Each of these claims includes the limitation "wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter". Upon reconsideration, the outside of the wall surface of the Ersek (3,657,744) fixation sleeve is not considered to be smooth. The Ersek fixation sleeve is formed of expanded metal. A sample of conventional expanded metal was shown to the examiner during the July 8, 1998 interview. The sample is depicted in Exhibit 1 of the July 22, 1998 amendment. The sample has the same basic shape as that shown in figure 5 of Ersek. As one follows the outside surface of one of the strands of the sample, one meets an abrupt obstacle at the bridge (at the junction of the strands) since the bridge has a thickness which is twice as great as the strand. The outside of the wall surface of the Ersek fixation sleeve includes a multitude of these obstacles (one at each bridge), making it rough rather than smooth. Therefore, the Ersek reference fails to meet the smooth surface limitation quoted above. Further, making the outside of the Ersek

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fixation sleeve smooth rather than rough would be contrary to the teachings of Ersek since the rough surface formed by narrow outwardly projecting edges is intended to embed itself into the tissue wall upon expansion of the sleeve (col. 3, lines 1-6).

Claims 35 and 37

Claims 35 and 37 have been amended. These claims, prior to the amendment, were rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus (4,787,899) in view of Ersek (3,657,744). These claims were also rejected under 35 U.S.C. 103(a) as being unpatentable over Kononov (U.S.S.R. 660,689) in view of Ersek (3,657,744). These rejections are no longer considered to be proper. Amended claims 35 and 37, like unamended claims 23 and 34, include the limitation "wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter". Ersek fails to meet this limitation as indicated above. Even if an Ersek type of fixation sleeve were placed on the Lazarus or Kononov graft, its outside wall surface would not be smooth as claimed.

Claims 35 and 37, prior to the amendment, were also rejected under 35 U.S.C. 103(a) based upon Kononov in view of Kornberg (4,617,932). This rejection is no longer considered to be proper. Claims 35 and 37 include the limitation "the wall surface having a substantially uniform thickness". Even if the Kornberg type of struts 12 were included in the Kononov prosthesis, the prosthesis

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would not have a substantially uniform thickness as now claimed since the thickness of the prosthesis at the struts would be substantially greater than the thickness of the prosthesis where no struts were located.

Claims 35 and 37, prior to the amendment, were also rejected under 35 U.S.C. 103(a) based upon Lazarus. This rejection is no longer considered to be proper. Even if the combination of the Lazarus graft 12 and staples 16 is considered to be the claimed prosthesis, the combination does not have a substantially uniform thickness as now claimed, since the thickness of the wall of the prosthesis where the staples overlies the graft 12 includes the thickness of the staples 16 plus the thickness of the graft 12 while the thickness of the wall of the prosthesis at areas where the staples do not overlie the graft 12 is only the thickness of the graft 12.

Claim 51

Claim 51 is a new claim. This claim is even more limited than original claims 13 and 24. Claim 51, like unamended claims 23 and 34, includes the limitation "wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter". Ersek fails to meet this limitation as indicated above.

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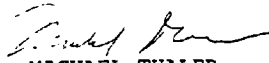
Art Unit: 3731

In Conclusion

As indicated above, none of the claims can be properly rejected using the same references and grounds of rejection applied in the first Office Action. No other combination of these references can be used to properly reject any of the claims as they now stand. In addition to these references, all of the other references of record have been carefully considered. None of the references of record, whether considered separately or in any combination, can be used to properly reject any of the claims as they now stand.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981.

mht
August 25, 1998


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731

PWRAP 003260

Exhibit V

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

FILED
U.S. DISTRICT COURT
DISTRICT OF DELAWARE
2005 JAN 25 PM 4:18

CORDIS CORPORATION,

Plaintiff,

v.

MEDTRONIC VASCULAR, INC.,
BOSTON SCIENTIFIC CORPORATION,
and SCIMED LIFE SYSTEMS, INC.,

Defendants.

Case No. 97-550-SLR
(Consolidated)

**BOSTON SCIENTIFIC CORPORATION AND
BOSTON SCIENTIFIC SCIMED, INC.'S MOTIONS *IN LIMINE*
(NOS. 1 THROUGH 7)**

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January 25, 2005

**OPENING BRIEF IN SUPPORT OF BSC’S MOTION *IN LIMINE* NO. 5:
TO PRECLUDE CORDIS FROM OFFERING EVIDENCE RELATING TO
THE NONOBVIOUSNESS OF CLAIM 44 OF THE ’762 PATENT**

* * * * *

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<i>Mossman v. Broderbund Software, Inc.</i> , Case No. 98-71244-DT, 1999 U.S. Dist. LEXIS 8014 (E.D. Mich. May 18, 1999).....	2
Statutes	
35 U.S.C. § 103 (2004).....	1, 2
35 U.S.C. § 305 (2004).....	1, 2, 3

BSC respectfully moves *in limine* to preclude Cordis from offering evidence relating to the issue of whether claim 44 of the '762 patent is invalid for obviousness under 35 U.S.C. § 103, because that issue is moot, and such evidence would be confusing and unfairly prejudicial to BSC.

FACTS

The '762 patent in suit is a continuation-in-part of the parent application that issued as the '665 patent. Although the '665 patent broadly claims the general concept of balloon expandable stents and their use, Cordis has never asserted, and long ago covenanted not to assert, the '665 patent against BSC. Unlike the '665 patent, the '762 patent is a narrow patent that focuses on Dr. Palmaz's slotted tube stent and its use.

At the previous trial in 2000, the only claims of the '762 patent that Cordis asserted against the NIR stent were device claim 23 and method claim 44. Only claim 23 is at issue in the new trial.

At the previous trial, the jury found that BSC had contributorily infringed the method of claim 44, but that claim 44 was invalid because Cordis had added the claim solely to cover competitive stents, such as the NIR stent, which is not a permissible reason for adding a claim in a reexamination under 35 U.S.C. § 305. After trial, this Court denied BSC's motion for JMOL of noninfringement of claim 44, and denied Cordis' motion for JMOL that claim 44 was not invalid under 35 U.S.C. § 305. *See Cordis Corp. v. Medtronic AVE, Inc.*, 194 F. Supp. 2d 323, 349-53 (D. Del. 2002).

Despite this final determination by this Court that claim 44 is invalid, Cordis' experts apparently plan to testify that both claims 23 and 44 of the '762 patent are not

invalid for obviousness under the new claim construction. (7/30/04 Buller report (Ex. A) at 2, 31-33, 37-38; 7/30/04 Collins report (Ex. B) at 3-4, 6, 21, 26.)

ARGUMENT

Cordis should be precluded from offering evidence relating to the issue of whether claim 44 of the '762 patent is invalid for obviousness under 35 U.S.C. § 103, because that issue is moot, and such evidence would be confusing and unfairly prejudicial to BSC.

The only obviousness issue that is justiciable at this stage is the issue of whether claim 23 is obvious under the new claim construction. The issue of whether claim 44 is obvious is moot because claim 44 has been finally determined to be invalid under 35 U.S.C. § 305. *See Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1122 (Fed. Cir. 2000) (affirming district court's decision that the claims of the patent-in-suit are obvious over the prior art and not addressing the issue of whether the claims are invalid based on public use as moot); *Mossman v. Broderbund Software, Inc.*, Case No. 98-71244-DT, 1999 U.S. Dist. LEXIS 8014 (E.D. Mich. May 18, 1999) (granting defendants' motion for summary judgment of invalidity, finding that claims of the patent-in-suit are invalid as anticipated and indefinite, but denying defendants' motion for summary judgment of invalidity for failure to disclose best mode as moot). Indeed, the issue of whether claim 44 is obvious will remain moot unless and until Cordis successfully appeals this Court's decision not to set aside the verdict that claim 44 is invalid under 35 U.S.C. § 305. If and when that occurs, depending on the posture of the case at that time, the issue of whether claim 44 is obvious may need to be resolved, but the Court cannot and should not attempt to address that contingency now.

To permit Cordis to offer evidence regarding the nonobviousness of claim 44 also would needlessly confuse the jury by injecting extraneous issues into the trial that are not properly justiciable. Moreover, such evidence would confuse the jury in a manner that would be unfairly prejudicial to BSC, because it would divert the jury's attention from the obviousness of the narrow device of claim 23, which is properly in issue, to the obviousness of the general method of implanting balloon expandable stents, which is not properly in issue. The general method of implanting balloon expandable stents is the subject of the parent Palmaz '665 patent, which Cordis long ago agreed not to assert against BSC. Cordis should not be permitted to circumvent this covenant by injecting claim 44 into the trial in an attempt to inflate Dr. Palmaz's contribution and confuse the jury into thinking that the general method of implanting balloon expandable stents is in issue. The only issue properly before the jury is whether the narrow device claimed in claim 23 would have been obvious.

CONCLUSION

For the reasons set forth above, BSC respectfully requests that the Court grant its motion *in limine* no. 5.

Exhibit

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,

Plaintiff,

V.

MEDTRONIC VASCULAR, INC., BOSTON
SCIENTIFIC CORPORATION, and SCIMED
LIFE SYSTEMS, INC.,

Defendants.

**CONFIDENTIAL:
FILED UNDER SEAL**

C.A. No. 97-550-SLR

MEDTRONIC VASCULAR, INC.,

Plaintiff,

V.

**CORDIS CORPORATION, JOHNSON & JOHNSON
and EXPANDABLE GRAFTS PARTNERSHIP,**

Defendants.

C.A. No. 97-700-SLR

CORDIS' RESPONSE IN OPPOSITION TO BSC'S MOTIONS *IN LIMINE*

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Attorneys for Cordis Corporation

Dated: February 7, 2005

153201.1

**CORDIS' RESPONSE IN OPPOSITION TO BSC'S MOTION *IN LIMINE* NO. 5,
TO PRECLUDE CORDIS FROM OFFERING EVIDENCE
RELATING TO THE NONOBVIOUSNESS OF CLAIM 44**

BSC's *In Limine* Motion No. 5 seeks an order barring Cordis from introducing evidence relating to the nonobviousness of claim 44 of the '762 patent. Cordis does not oppose this motion, and does not intend to offer evidence on that subject.

Claim 44 (unlike claim 23) does not include the "substantially uniform thickness" limitation. As a result, the jury's verdict of infringement of claim 44 was not affected by the revised claim construction. In Cordis' view, issues involving infringement or validity of claim 44 are outside the scope of this trial.

At trial in 2000, the jury found that claim 44 was infringed by BSC, but was invalid under Section 305 of the patent statute, 35 U.S.C. § 305. In ruling on post-trial motions, this Court denied BSC's JMOL motion on infringement for claim 44. Cordis v. Medtronic AVE, 194 F. Supp. 323, 349-51, and denied Cordis' motion for JMOL on validity under § 305. Id. at 351-53. Although this Court agreed with Cordis that validity under § 305 was a question of law for the court, not a jury question, id. at 351-52, it found that "claim 44 was added solely to cover competitors' stents, and not for a permissible reason under § 305." Id. at 353. Cordis has not yet had an opportunity to appeal this Court's ruling on claim 44 validity.

Cordis agrees that the issues for trial do not include the validity of claim 44.

Exhibit

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1 - VOLUME C -
2 IN THE UNITED STATES DISTRICT COURT
3 IN AND FOR THE DISTRICT OF DELAWARE
4
5 CORDIS CORPORATION, : CIVIL ACTION
6 Plaintiff :
7 vs. :
8 :
9 MEDTRONIC AVE, INC., BOSTON :
10 SCIENTIFIC CORPORATION and :
11 SCIMED LIFE SYSTEMS, INC., :
12 Defendants : NO. 97-550 (SLR)
13 :
14 BOSTON SCIENTIFIC CORPORATION : CIVIL ACTION
15 and SCIMED LIFE SYSTEMS, INC., :
16 Plaintiffs :
17 vs. :
18 :
19 ETHICON, INC., CORDIS CORP. :
20 and JOHNSON & JOHNSON :
21 INTERVENTIONAL SYSTEMS CO., :
22 Defendants : NO. 98-19 (SLR)
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1 properly rejected using the same references and grounds
2 of rejection applied in the first office action.

3 That was what Mr. Badenoch was asking you
4 about?

5 A. Yes.

6 Q. The arguments that the examiner made in the first
7 office action he now says, none of the claims can be
8 properly rejected using the same -- using those references.

9 Is that the point?

10 A. That's absolutely right. This is the examiner's
11 conclusion at the end of this process. The examiner
12 looked at Ersek and all of these thing and said none of
13 these things can reject Dr. Palmaz's invention.

14 Q. And then he says, no other combination of these
15 references can be used to properly reject any of the
16 claims as they now stand. In addition to these
17 references, all of the other references of record have
18 been carefully considered. None of the references of
19 record, whether considered separately or in any
20 combination, can be used to properly reject any of the
21 claims as they now stand.

22 What references did you understand the
23 examiner was referring to?

24 A. The three things that have been raised, and in
25 particular, Ersek, but also Lazarus and Russian reference

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1 called Kononov.

2 Q. He says all of the other references of record have
3 been carefully considered.

4 Did that include --

5 A. There's a huge -- a huge list. If you look at the
6 re-examination, I can't remember if it's in evidence,
7 but if you look at the '762 re-examination, there's a
8 huge list of documents and references and things that
9 were put in front of the examiner to consider and this
10 is a vast list, including Ersek, Kononov and Lazarus.

11 Q. Did it include Dotter's disclosure of percutaneous
12 angioplasty?

13 A. Yes. His 1969 disclosure, it included that.

14 Q. Did it include Grunzig's pioneering disclosure of
15 balloon angioplasty?

16 A. Yes.

17 Q. Did it include all the self-expanding stents you've
18 been talking about?

19 A. Yes.

20 Q. All right. Now, the examiner emphasizes the word
21 none. I would just like to ask you whether you agree
22 with that emphasis?

23 A. Absolutely, I do. I've looked at all of these
24 documents myself, and I don't believe that any of them
25 on their own or combined together made Dr. Palmaz's

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1 invention obvious or anticipated.

2 Q. And why is it that you believe that Dr. Palmaz's
3 combination of elements in Claim 23 is not obvious?

4 A. Because it is a truly unique combination. You
5 can't as I said previously think did Dr. Palmaz invent
6 slots, did he invent a tube, did he invent metal. What
7 he invented was this unique combination that you put
8 together to allow patients to be treated without major
9 surgery, to allow a procedure to be done through the
10 lumen without opening up exposing, cutting or doing any
11 of the sort of things that Ersek taught.

12 Q. Let's take a look at Claim 23 again.

13 Now, Mr. Badenoch asked you some questions
14 about commercially successful coronary balloon expandable
15 stents. And I'm not sure he was focusing exactly on
16 what your testimony was.

17 Do you have an opinion as to the relationship
18 between the elements set forth in Claim 23 and successful
19 balloon expandable coronary stents?

20 A. Yes. I believe that all of the successful balloon
21 expandable coronary stents use this unique combination of
22 elements as put forward in Dr. Palmaz's Claim 23 of his
23 '762 patent. They use this combination of elements in
24 the way that Dr. Palmaz taught.

25 Q. Do they all have first diameters for intraluminal

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1 delivery?

2 A. Yes. They all have first small diameters to allow
3 you to deliver along the lumen, to avoid surgery.

4 Q. Do they all have second expanded and deformed
5 diameters upon the application of radially outwardly
6 extending force that's variable and used to expand the
7 lumen?

8 A. Yes, they do.

9 Q. And structurally, do they all have a thin-walled
10 tubular member with longitudinal slots?

11 A. Yes. This is exactly what Dr. Palmaz taught. All
12 of the commercially available balloon expandable coronary
13 stents have the longitudinal slots that can open up like
14 an expansion joint to allow it to open up to a larger
15 size and support the body passageway in the coronary
16 artery.

17 Q. Mr. Badenoch showed you the table of contents of one
18 of these handbooks of coronary stents.

19 Mr. Croce gave some testimony about the second
20 generation of coronary stents that entered the U.S. market
21 in 1977 and 1978.

22 What stents were those?

23 A. Sorry. 19 --

24 Q. 1997 and 1998, the second generation -- when the
25 second generation of coronary stents entered the U.S.

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1 market.
2 A. NIR stent, AVE stent, they all came in the late
3 1990s.
4 Q. All right. Together with Cordis, do they dominate
5 the stent market?
6 A. Yes.
7 Q. Let's take a look at the stents that entered the
8 market in 1997.
9 AVE's stent, does it have longitudinal slots
10 as described by Dr. Palmaz?
11 A. Yes, it does.
12 Could we possibly turn the lights down? I
13 can't see that well the screen.
14 Thank you.
15 Q. Can you point this out?
16 A. Here are shown three of the commercial leaders over
17 the years and here is the AVE product with a closeup of
18 it here with slots, longitudinal slots running along the
19 length of the stent. Here is the ring structure I've
20 talked about previously.
21 Here is the NIR stent, the BSC stent we
22 talked about during this litigation. Here are the slots
23 that allow it to expand and it runs around the
24 circumference as I talked about previously.
25 Here's another stent, a Multi-Link stent by

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1 Guidant, ACS company. Again, here are the slots running
2 around and that allow it to open up. All of the
3 commercially expandable commercially balloon expandable
4 stents use the invention of a slotted tube structure that
5 can open up to a second diameter to support the passageway.
6 Q. Let's add Cordis' BX velocity. Does Cordis' BX
7 Velocity use the slots of Claim 23?
8 A. Yes. It's the one that has the right to do so.
9 It practices Dr. Palmaz's invention. Here is the stent,
10 the BX velocity. It's the same basic stent that produces
11 the Cipher, the drug-eluting stent and here is the slot,
12 here it's running around the circumference and this is
13 what allows it to expand and support the wall.
14 And you can see the similarity. Here is the
15 Cordis product. Here's the Boston SciMed product.
16 Here's the AVE product, here's the ACS product. They
17 are all using Dr. Palmaz's invention.
18 Q. Is there any dispute in this case that BSC's NIR
19 stent has longitudinal slots?
20 A. No. I don't think there's any dispute.
21 Q. In fact, is there any dispute in this case about
22 any limitation at all except whether the NIR stent has
23 a wall substantially -- of substantially uniform
24 thickness?
25 A. My understanding is that Boston SciMed are not

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1 disputing any other claim limitation other than the
2 substantially uniform thickness that we've talked about
3 at length.
4 Q. Does the NIR stent have a wall of substantially
5 uniform thickness?
6 A. Yes, it does.
7 MR. DISKANT: Thank you.
8 Nothing else, your Honor.
9 THE COURT: All right. You may step down.
10 THE WITNESS: Thank you.
11 THE COURT: Thank you.
12 (Witness excused)
13 - - -
14 MR. DISKANT: With this, your Honor, our
15 presentation of evidence is completed and Cordis rests
16 its case.
17 Thank you, ladies and gentlemen.
18 THE COURT: All right. Let's save any other
19 discussions until our next break.
20 MR. BADENOCH: Fine, your Honor.
21 Ladies and gentlemen, you've now heard one
22 side of the case and we're going to present our case.
23 Our first witness is Paul Laviolette. And he is the
24 Chief Operating Officer of Boston Scientific. He's going
25 to tell you a little bit about Boston Scientific and

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1 discuss its sale of the NIR stent. He has been a member
2 of Boston Scientific's Senior Management Team and
3 Executive Committee since 1994, before we began selling
4 the NIR stent.
5 And he'll be examined by my partner, Walt
6 Hanley.
7 - - -
8 DEFENDANTS' TESTIMONY
9
10 ... PAUL ARTHUR LAVIOLETTE, having
11 been duly sworn as a witness, was
12 examined and testified as follows ...
13 MR. HANLEY: Good afternoon, ladies and
14 gentlemen.
15 DIRECT EXAMINATION
16 BY MR. HANLEY:
17 Q. Good afternoon, LaViolette.
18 Would you please tell us by whom you're
19 currently employed?
20 A. I'm employed for Boston Scientific Corporation.
21 Q. And how long have you been with the company?
22 A. Since 1994, so going on 12 years.
23 Q. What are your current duties and responsibilities?
24 A. Well, I'm the Chief Operating Officer at BSC, so
25 my responsibilities encompass all day-to-day operating

Exhibit

Y

- VOLUME A -
 IN THE UNITED STATES DISTRICT COURT
 IN AND FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,
 Plaintiff
 vs.
 MEDTRONIC AVE, INC., BOSTON
 SCIENTIFIC CORPORATION and
 SCIMED LIFE SYSTEMS, INC.,
 Defendants
 NO. 97-550 (SLR)

BOSTON SCIENTIFIC CORPORATION
 and SCIMED LIFE SYSTEMS, INC.,
 Plaintiffs
 vs.
 ETHICON, INC., CORDIS CORP.
 and JOHNSON & JOHNSON
 INTERVENTIONAL SYSTEMS CO.,
 Defendants
 NO. 98-19 (SLR)

CORDIS CORPORATION,
 Plaintiff
 vs.
 MEDTRONIC AVE, INC., BOSTON
 SCIENTIFIC CORPORATION and
 SCIMED LIFE SYSTEMS, INC.,
 Defendants
 NO. 98-197 (SLR)

Wilmington, Delaware
 Thursday, March 17, 2005
 9:35 o'clock, a.m.

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury
 Valerie J. Gunning and
 Leonard A. Dibbs,
 Official Court Reporters

1 APPEARANCES:

2 ASHBY & GEDDES
 BY: STEVEN J. BALICK, ESQ.

3 -and-

4 PATTERSON, BELKNAP, WEBB & TYLER LLP
 BY: GREGORY L. DISKANT, ESQ.,
 EUGENE M. GELERNTER, ESQ.,
 WILLIAM F. CAVANAUGH, JR., ESQ.,
 MICHAEL TIMMONS, ESQ. and
 SCOTT HOWARD, ESQ.
 (New York, New York)

5 -and-

6 JOHNSON & JOHNSON
 BY: ERIC L. HARRIS, ESQ.

7 Counsel for Cordis Corporation

8 YOUNG, CONAWAY, STARGATT & TAYLOR
 BY: JOSY W. INGERSOLL, ESQ.

9 -and-

10 KENYON & KENYON
 BY: GEORGE BADENOCH, ESQ.,
 MARK CHAPMAN, ESQ. and
 WALTER HANLEY, ESQ.
 (New York, New York)

11 Counsel for Boston Scientific
 Corporation

12 ---

P R O C E E D I N G S

(Proceedings commenced at 9:35 a.m.)

THE COURT: Good morning, counsel.
 (Counsel respond "Good morning, your Honor.")

THE COURT: Deja vu all over again.
 We see jurors in the back. So, as soon as
 they're kind of gathered, we'll bring them in. I
 understand that there are no issues, problems before
 jury selection, so we'll just go forward.

MR. BADENOCH: Your Honor, one --

THE COURT: Yes?

MR. BADENOCH: -- noncontroversial on the
 voir dire. Albert Brenneisen is not here. Walt Hanley
 is. So on Page 6, when you read counsel...

THE COURT: Well, I don't generally read.
 They have the list. So I can add that name.
 Let me just make sure I have it right.
 H-a-n-l-e-y?

MR. HANLEY: Correct, your Honor.

THE COURT: All right.
 (At this point the prospective jurors were
 brought into the courtroom.)

THE COURT: Good morning, ladies and gentlemen.
 I'm Judge Robinson and I will be presiding over a trial
 for which a jury is about to be drawn in the case
 captioned Cordis Corporation versus Boston Scientific
 Corporation, et al. Briefly stated, this is a patent
 action, arising under the patent laws of the United
 States, involving stents, which are medical devices
 implanted in arteries.

The trial will last five days. I time my
 trials so the attorneys have to complete their trial
 presentations within these limits. However, jury
 deliberations may require you to be present longer than
 five days.

Our trial days will run approximately from
 9:30 a.m. to 4:30 p.m.

In light of this brief summary, I'm going to
 ask you certain questions, the purpose of which is to,
 one, enable the Court to determine whether any prospective
 juror should be excused for cause and, two, to enable
 counsel for the parties to exercise their individual
 judgment with respect to peremptory challenges, that is
 challenges for which no reason need be given by counsel.

If any of you answer any question yes, please
 stand up and, upon being recognized by the Court, state
 your juror number.

1 trial: My partner, Walt Hanley, my partner, Mark
 2 Chapman, and Josy Ingersoll from the firm here, Young
 3 Conaway in Wilmington.
 4 Boston Scientific is not as big as Johnson &
 5 Johnson. We don't sell baby oil or Band-Aids or those
 6 things, but it was founded in 1979 specifically to go
 7 into the business of minimally invasive surgery, the
 8 kind of things you've been seeing on the screen with
 9 those animations, where instead of having open, traumatic
 10 surgery, you implant small devices, you have these
 11 procedures where you use a catheter that goes in through
 12 the blood vessel to the location. That's our business.
 13 Boston Scientific specializes in small implantable
 14 devices, minimally invasive surgery. And we've been in
 15 that business longer than Johnson & Johnson.
 16 We have with us here from Boston Scientific
 17 the Chief Patent Counsel in charge of this, Mr. Gillman.
 18 And I would also say that the Boston Scientific, as you
 19 heard, did invest in this technology. The Nir stent
 20 that's accused in this case, which Boston Scientific
 21 purchased, was developed by a small innovative company
 22 called Medinol Limited. You heard that that was a good
 23 product, even from the plaintiffs.
 24 And we have the Chief Technical Officer here
 25 of Medinol as well, doctor Jacob Richter.

1 Now, I listened to the opening statement of
 2 plaintiff's counsel and I thought it was a bit one-sided
 3 but, you know, I'm biased. I'm on the other side. I'm
 4 sure you were expecting that. You know you're going to
 5 hear the other side from me.
 6 He kind of made it sound like this great
 7 development of going from open-heart surgery all the way
 8 up to these wonderful procedures we have today was all
 9 basically attributable to Dr. Palmaz. And I think you
 10 probably realize that's a bit one-sided. Dr. Palmaz did
 11 make a contribution, no question. But so did many
 12 others. Many people contributed to this thing before Dr.
 13 Palmaz and many important contributions were made after,
 14 including contributions by Boston Scientific.
 15 Johnson & Johnson is not the only company to
 16 invest millions of dollars in risky new medical
 17 technology. That's our business. Boston Scientific
 18 has invested comparable amounts in risky new
 19 technologies.
 20 The -- let me give you just a few important
 21 examples of how this development actually occurred. Dr.
 22 Palmaz didn't invent stents and he's not going to say
 23 that he did. The inventor of stents is Dr. Charles
 24 Dotter, who back in 1969, he also invented, incidentally,
 25 this is his coil stent you see on the screen there, he

1 also invented this procedure, where you go into the
 2 blood vessel with a guide wire and you put things over
 3 the wire to locate the site like a stent, this minimally
 4 invasive procedure.
 5 And Dr. Palmaz also did not invent the first
 6 controllably expandable stent. There is another device
 7 in the prior art that you're going to hear a lot about
 8 that was invented by Dr. Robert Ersek. Dr. Ersek had
 9 an expandable metal tube, you're going to learn it's
 10 got almost all of the very same features as Dr. Palmaz's
 11 first tube. It's expanded. It's controllable. You put
 12 it into the end of a lumen and he used it in surgical
 13 procedures to attach a graft and put it into the end of
 14 a lumen.
 15 Dr. Palmaz also did not invent -- that was
 16 1972, incidentally. Dr. Palmaz did not invent balloon
 17 angioplasty. The real key to these procedures, as you
 18 heard, is the invention of Dr. Andreus Gruntzig. Dr.
 19 Gruntzig, he's the one that came up with the idea of
 20 balloon angioplasty, where you go in through the blood
 21 vessel like this instead of open-heart surgery. You
 22 have this balance balloon, as you saw on counsel's
 23 animation, which opens the artery up, with a high-pressure
 24 balloon. That was Dr. Gruntzig.
 25 So you have all these procedures and

1 inventions preceding Dr. Palmaz.
 2 What did Dr. Palmaz do? Well, he did have a
 3 very good idea. What he did was to take an expandable
 4 tube, like Ersek, put it on the balloon, and then go in
 5 and expand it with the balloon at the same time and
 6 implant it that way. That's what he did. That's the
 7 balloon expandable stent invention. And it was a good
 8 idea. And he has been paid handsomely for it.
 9 But that is not what this case is about.
 10 Not only is Cordis' story a bit one-sided, it's off
 11 point, too.
 12 This case is about a single claim in the
 13 patent that you have in your books there and this claim
 14 is different. It's not the balloon expandable stent
 15 invention.
 16 Can we put up the claim?
 17 This is the claim that counsel put up. You
 18 will be hearing about this throughout the trial.
 19 There are two parts to it. It's a combined
 20 claim. You see the number 13 at the top. Then there's
 21 a whole list of things. I'm not going to read it now.
 22 Then there's 23.
 23 And 23 refers to 13. So although Claim 23 is
 24 the only asserted claim in this case, it includes the
 25 elements of 13 and 23.

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1 Now, this has got a lot of medical jargon in
2 it here, but briefly, the point is this. This claim
3 covers an expandable metal tube that you stick into an
4 artery or some other vessel, blood vessel, and it has
5 certain structural features. And that's all.
6 Let me show you. If we compare it to -- this
7 is Dr. Palmaz's preferred tube in his patent. Basically,
8 when it says, this says it's expandable. Okay.
9 Intraluminal. That means a lumen is any body passageway.
10 Vascular means it's a blood vessel. Graft means it hold
11 open and supports.
12 Then you have a bunch of elements: A
13 thin-walled tubular member. Well, it's a thin-walled tube.
14 It's got first and second ends.
15 It's got a wall surface between the two ends.
16 The wall surface has to be substantially
17 uniformly thick. We're going to talk about that, as you
18 can gather from the opening.
19 It has to have a plurality of slots in it.
20 It has to have a first diameter that is small
21 enough that you can put it in the lumen. You have to be
22 able to deliver it in the lumen.
23 And it has to have a second diameter that
24 is -- that you -- that you get when you expand it.
25 Now, later on we'll also have a smooth surface,

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1 but just pause here for a second.
2 What's interesting is what you don't see in
3 this claim. This is not about -- first of all, it's not
4 about coronary applications. The word coronary is nowhere
5 in the claim, the thing that made all this money,
6 Palmaz/Schatz. That's a coronary stent. This one is not
7 limited to coronaries at all.
8 Second, you don't see the word balloon in
9 this claim anywhere. This claim does not limit it to a
10 balloon expandable stent.
11 ---
12 MR. BADENOCH (Continuing): This is the
13 expandable tube, just like Ersek, except that there's a
14 few features on the wall surface, smoothness and
15 thickness, that are different.
16 What it says about the force to expand the
17 balloon. It doesn't say to expand the balloon. It says
18 any radially outwardly extending force. With this claim
19 you can put a balloon in here and expand --
20 ---
21
22
23
24
25

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1
2 MR. BADENOCH (Continuing): You can put a
3 mechanical tool in and expand it. You can expand it
4 with anything that you can expand and plastically expand
5 and deform that, as much as you want.
6 And that's important for a number of reasons.
7 You're going to be asked basically two questions in this
8 case. The questions are is this one asserted claim?
9 It's the only claim that's asserted in the case. Is
10 this claim valid and is it infringed by the Nir stent?
11 Now, on validity, just to make the point
12 clear, the question you'll be asked is, is the
13 expandable stent described in Claim 23 obvious? It's
14 an expandable tube. We're going to be comparing it to
15 Ersek's expandable tube and talking about those
16 differences and that's going to be your question.
17 The question is not is Dr. Palmaz's balloon
18 expandable stent invention obvious. His idea of putting
19 the stent on a balloon, delivering it intraluminally,
20 implanting at the same time, all of those ideas that
21 counsel talked about, that's not this claim. You're
22 not being asked to decide that question.
23 And we're certainly not here in court this
24 week to decide whether Dr. Palmaz is entitled to credit
25 for what he did do. Of course, he is, and he has

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1 received it, in spades. We'll come to that. But we're
2 here to discuss a much more limited issue.
3 The other thing I should point out as far as
4 the actual more balanced story, the -- after Dr. Palmaz,
5 I mean, Dr. Palmaz had a great idea of putting a stent
6 on a balloon. His tube itself, well, you saw it, is kind
7 of a rigid tube and by itself, that wasn't really such a
8 great idea. It was okay for a while, while it was alone
9 on the market, but when newer stents came along,
10 clearly, they were better. No question.
11 You heard, for example, about the skepticism.
12 Yes, doctors were very skeptical. But what were they
13 skeptical about?
14 They weren't skeptical about this claim.
15 They were not skeptical. They were skeptical about the
16 fact, as counsel explained, leaving a little metal
17 device in the artery where you have blood flow. That
18 was what they were skeptical about. That's what SciMed
19 was worried about. That's what all these other
20 companies were worried about. And they were worried
21 about that for good reason.
22 If you have metal in the bloodstream, you
23 create clots. It's called thrombosis, and that can be
24 a serious problem. And the idea of putting these metal
25 stents in, okay, it would help hold it open, but if the

1 metal hung in the artery, you would get thrombosis,
2 and that's what they were worried about. They were not
3 skeptical about if you have this kind of tube, and if
4 you put a force inside it and blow it up, would those
5 slots turn into diamonds?

6 You know, that's this. If you take -- this
7 is kind of like a child's gate at the top of the stairs
8 and you apply force. Look. These slots open into
9 diamonds. If you have a cylinder, that is what happens.

10 Nobody was skeptical of that. That's obvious.
11 Everybody learns this when they are three. Okay?

12 So what the doctors were worried about was
13 the metal in the artery. And Dr. Palmaz didn't solve
14 that problem. Dr. Palmaz -- I mean doctor -- Antonio
15 Columbo came up with a solution. He realized, and he
16 published this later, he realized that if you have new
17 balloons with a lot more force so that you can put the
18 metal, press the stent much more firmly into the artery,
19 which is elastic, so that the metal gets covered, then
20 you can avoid what they were doing with early stenting.

21 Early stents, they put them in and because
22 of this thrombosis, they had to use a very harsh drug
23 regimen. It was called Coumadin. It's a very
24 aggressive blood thinner. It's also called Warfarin.
25 The same stuff is used as a rat poison. It's very

1 partner, not Dr. Palmaz. In fact, Dr. Palmaz actually
2 opposed that idea, as he'll agree. He will agree he
3 turned down the idea. The flexibility contribution,
4 key to the coronary market where all the money came
5 from, that came from Dr. Schatz.

6 So my point here is that Dr. Palmaz can't be
7 given credit for everything. He's given tremendous
8 credit for what he did do. This claim, however, is on
9 the expandable tube part and that's not something that
10 I think you're going to find valid when we present all
11 the evidence.

12 Now, since then, you heard about other
13 stents are on the market. They've talked about they have
14 newer models now. That's true. They have BX Velocity.
15 They have Cipher. And in between there's something
16 interesting. In between, when the -- this original tube
17 that they had, the Palmaz/Schatz stent and the new
18 Cordis products, other products, including the Nir, had
19 the market. Why? Because of those other features that
20 turned out to be extremely important.

21 The commercial success that they are going to
22 talk about, it's not all based on Dr. Palmaz. You know
23 it's not because otherwise, how could one stent that
24 they put on, the Palmaz invention, suddenly disappear,
25 suddenly get replaced by ours and others and then get

1 harsh. And you'll find in these Stress and Benestent
2 studies that they talk about, yes, there was improvement,
3 modest, but there was improvement that the stent held
4 the artery open longer. That's true. But you'll also
5 see in the very same studies the patients had to stay in
6 the hospital longer because of this Coumadin treatment
7 and the complications and the side effects.

8 And that wasn't Dr. Palmaz's contribution.
9 Dr. Columbo, very famous interventional cardiologist in
10 Italy, came up with that, published it when other
11 doctors began to realize how you could do this. By having
12 the balloons inflated with more pressure, that's when
13 these stents started to take off.

14 That's another thing. The big market that
15 made all the money here was coronaries. And Dr. Palmaz
16 is not a cardiologist and he did not invent the design
17 that is the coronary stent. Dr. Palmaz's tube, that's
18 too rigid. That's used in peripherals. It's too rigid
19 to put in a coronary. There was a flexibility problem.
20 In order to come up with that Palmaz/Schatz stent, they
21 had to find some way to make it more flexible and they
22 did. They had this little thing that flexes. It's like
23 two boxcars where you saw a link there. They didn't
24 show it, but you could see it on the stent they put up.

25 And that idea came from Dr. Schatz, his

1 replaced again by theirs?

2 Today everybody is making drug-eluting
3 stents. Boston Scientific is the leader in that. Cordis
4 has a product, too. They, in fact, improved restenosis
5 much more than the Palmaz stent.

6 So the story as a whole, many contributors.

7 Now, why is it so important to pay attention
8 to what this claim actually says, the one claim in the
9 case? Three reasons.

10 First, it's extremely important because it's
11 why you realize that all of this praise, the story you
12 heard, is off point. It's interesting background about
13 Dr. Palmaz, but it's not what the case is actually going
14 to be about.

15 All this praise that you heard of Dr. Palmaz,
16 it's not about the design of that tube. It's about his
17 contribution of combining the tube with the balloon, the
18 balloon expandable stent, which is not what this claim
19 is limited to.

20 The skepticism about -- of the doctor, that's
21 not about this tube either. They all know it could be
22 expanded. It was about the problem of metal in the
23 bloodstream, which was answered by Dr. Columbo.

24 The commercial success, it's not to the tube
25 either.

1 So in this sense, Cordis' story is a little
2 bit of a smokescreen. There's a bait and switch here.
3 Don't be taken in by it. Dr. Palmaz deserves all of
4 the credit he has been given for what he did do, and we
5 agree with that, but the claim asserted in this case is
6 not for that combination.

7 It's also important because this claim is
8 invalid. Put simply, it's too broad because it's not
9 limited to what was Dr. Palmaz's balloon expandable
10 stent invention. Maybe just to explain, under the
11 patent law, patents build on other patents. If you have
12 a patent on a combination, Dr. Palmaz is entitled to a
13 patent on the balloon expandable stent, to combined the
14 expandable stent with a balloon. He's entitled to that.
15 He's not entitled to a patent on any stent. Dr. Dotter
16 invented that years earlier.

17 He's not entitled to a patent on any
18 expandable tube or the expandable stent like Ersek.
19 Ersek did that first. He's certainly not entitled to a
20 patent on a balloon.

21 It's like if you have a patent on a roller
22 skate, because you invent the combination, you're
23 entitled to a patent on the roller skate, but you don't
24 get a patent on a shoe and you don't get a patent on
25 the wheels. Those are components. We're talking about

1 upon Cordis for the information and he has to accept,
2 when they tell him facts and submit affidavits and
3 evidence, he can't go out and hire his own experts.
4 He does not have an adversarial proceeding like you're
5 going to see. He does not have experts coming in on
6 both sides and being cross-examined like you will. He
7 does not have nearly the time to study this as you're
8 going to have. And that's why it's important.

9 There are a lot of cases -- the Patent Office
10 has issued over six million patents since it was founded.
11 They are issuing them at the rate of over a hundred
12 thousand a year now. They're not all valid, which
13 wouldn't surprise you. There are juries like you looking
14 at these all the time.

15 And in some cases, it's a question, the
16 examiner simply didn't know the prior art. Sometimes he
17 got information that turned out to be wrong. That's what
18 these cases are for.

19 This case actually turns out to provide a
20 perfect example. You are wondering, okay. They got a
21 patent on the balloon expandable stent. Fine. They
22 have other patents, other claims on that. They are not
23 asserted here. Okay.

24 How did they get a patent on an expandable
25 tube like this? How did they do that?

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1 here a component, the expandable tube, which is just
2 like Ersek and the prior art.

3 The other reason that this is important is
4 that because it's just like Ersek, they had to add
5 specific structural details, including the substantially
6 uniform thickness provision, into the claim, and that
7 limited their claim on that. And, as a result, we don't
8 infringe because the Nir stent simply doesn't meet that.
9 It does not meet that requirement at all.

10 Now, I'm going to come back to both of these
11 things in just a little bit more detail, but you may be
12 asking, first, the validity question. Why do you have
13 to decide this? You saw the video. The examiner has
14 already reviewed it. The video says you have to review
15 it again.

16 You may still be wondering why.

17 Well, the answer is because there's a patent
18 examiner in the office who does this but, frankly, the
19 examiners don't always get it right. They are very
20 busy. They have limited time and resources. They
21 conduct the proceedings, as you heard in the video, in
22 private. In other words, we're not there as competitors
23 to advise the examiner of any information. It's a
24 secret process going on between Cordis and the examiner,
25 and he has to accept what they tell him. He depends

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1 Well, it's interesting. The way they did it
2 the first time around, they turned in the application.
3 The examiner didn't know about Ersek, neither did Dr.
4 Palmaz. It went right through because they didn't find
5 any prior art that was like this until it was allowed.

6 Later, they discovered Ersek. And they knew
7 there was a problem, so they took it back to the Patent
8 Office for what's called a re-examination. The same kind
9 of process, but you have it examined again, because
10 there's new information.

11 They said, Ersek, this is Cordis, raised a
12 substantial new question of patentability and they were
13 right. It went back to the Patent Office and the
14 examiner agreed immediately and the examiner rejected
15 this claim, the whole thing as anticipated by Ersek.

16 He said, look, Ersek has got the same thing
17 you've got in the claim. This claim is simply for the
18 structure of the expandable tube. It does not say
19 balloon. It's not about the method of delivery. It's
20 not about any of those other ideas that he said. It's
21 just about the tube and he rejected that.

22 And you can tell why this is important
23 because this is the same examiner. He allowed it the
24 first time. The same examiner turns around in the
25 re-examination and now he rejects it.

Exhibit Z

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)	
<i>Plaintiff,</i>)	
v.)	
MEDTRONIC AVE, INC., BOSTON)	C.A. No. 97-550-SLR
SCIENTIFIC CORPORATION and)	
SCIMED LIFE SYSTEMS, INC.,)	
<i>Defendants.</i>)	
<hr/>		
MEDTRONIC AVE, INC.,)	
<i>Plaintiff,</i>)	
v.)	C.A. No. 97-700-SLR
CORDIS CORPORATION, et al.,)	
<i>Defendants.</i>)	
<hr/>		
BOSTON SCIENTIFIC CORPORATION,)	
<i>Plaintiff,</i>)	
v.)	C.A. No. 98-19-SLR
ETHICON, INC., et al.,)	
<i>Defendants.</i>)	
<hr/>		
CORDIS CORPORATION,)	
<i>Plaintiff,</i>)	
v.)	C.A. No. 98-197-SLR
BOSTON SCIENTIFIC CORPORATION, et al.,)	
<i>Defendants.</i>)	

**CORDIS' OPENING BRIEF IN SUPPORT OF ITS
MOTION FOR SUMMARY JUDGMENT ON OBVIOUSNESS**

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Dated: October 5, 2004
148423.1

flexible links] – does not distinguish the claimed combination from the prior art and as such, does not present a triable issue." Id. at *14.

The same reasoning applies here. Just as narrowing connectors to enhance flexibility was known in the art, so too the requirement for forming slots "in the wall surface of a tubular member, as by the removal of material" was "known in the art." Bourns, 537 F.2d at 493-94. Likewise, the need to set some tolerance was known in the art and the requirement limiting variations in thickness to less than 0.001 inch does not yield "new and unexpected results." Huang, 100 F.3d at 139. In the context of the combination as a whole, these requirements were not – and as a matter of law, could not be – the source of the '762 patent's validity at trial in 2000. Deleting them now does not warrant a new trial on obviousness. Westwood Chem., 525 F.2d at 1375; Bourns, 537 F.2d at 492-94; Medinol, 2004 WL 1243605 at *8-14; Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., ___ F.3d ___, 2004 WL 1925607 (Fed. Cir. Aug. 31, 2004) (adopting a broader claim construction than the one used at trial, but nonetheless reinstating the earlier verdict on obviousness).

II. AT TRIAL, DEFENDANTS WAIVED ANY OBVIOUSNESS CHALLENGE TO THE SCOPE THAT THE CLAIMS HAVE UNDER THE REVISED CLAIM CONSTRUCTION

There is another separate and independent reason why defendants are not entitled to a new trial on obviousness.

As noted above, Cordis asserted a scope of equivalents at trial that was as broad as the claims' literal scope under the revised claim construction. In responding to Cordis' proof of infringement under the doctrine of equivalents, defendants had an opportunity to challenge that claim scope. They had a strong incentive to do so, because they would have avoided a finding of infringement under the doctrine of equivalents if they had succeeded. Despite that opportunity and incentive, AVE decided not to raise the issue. BSC raised the issue, but then abandoned it.

By failing to pursue an obviousness challenge to the claim scope that Cordis asserted at trial under the doctrine of equivalents, AVE and BSC waived an obviousness challenge to that claim scope. They are not entitled to a "second bite at the apple." USA Petroleum, 13 F.3d at 1280, 1282; see also NLRB v. Dole, 334 F.3d at 490; EEOC v. Westinghouse, 925 F.2d at 631. Because that claim scope is as broad as the claims' literal scope under the revised construction, defendants' waiver applies here and bars their current obviousness challenge.

The facts giving rise to this waiver are all undisputed:

- The claim scope that Cordis sought at trial under the doctrine of equivalents was as broad as the claims' literal scope under the revised construction.
- AVE and BSC had the opportunity to raise the same obviousness challenge they want to raise now, by asserting that the prior art would have made this claim scope obvious to one of ordinary skill.
- At trial, AVE did not raise an obviousness challenge to that claim scope, despite an opportunity and incentive to do so.
- At trial, BSC raised the issue, but then abandoned it.

A. Defendants Had an Opportunity and Incentive at Trial to Raise an Obviousness Challenge to the Claim Scope that Cordis Asserted Under the Doctrine of Equivalents

If defendants had succeeded in an obviousness challenge to the claim scope that Cordis asserted under the doctrine of equivalents, that would have given them a complete defense to Cordis' charge of infringement under the doctrine of equivalents. Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677 (Fed. Cir. 1990); Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1380 (Fed. Cir. 2001); Marquip, Inc. v. Fosber America, Inc., 198 F.3d 1363, 1367 (Fed. Cir. 1999); Streamfeeder, LLC v. Sure-Feed Sys., Inc., 175 F.3d 974, 981-

85 (Fed. Cir. 1999); Jurgens v. McKasy, 927 F.2d 1552, 1561 (Fed. Cir. 1991). Defendants had both the opportunity and an incentive to raise that challenge.

In the teleconference on September 22, 2004, BSC emphasized that the jury was not instructed that 100% variations are an outer limit on the range of equivalents. In fact, as noted above, the issue was litigated, with Cordis affirmatively telling the jury that the 100% variation described by Ersek was not the Palmaz invention, and with BSC not even requesting a charge on that concession. More important for present purposes, the absence of such an instruction made it easier, not harder, for defendants to raise an obviousness challenge under Wilson Sporting Goods. After all, their two main references – Ersek and the Palmaz Abstract – have 100% variations in thickness. The Palmaz Abstract teaches a device made of "woven, stainless steel wire" with a double thickness at the cross-points, Ex. K, and as the Federal Circuit noted, the Ersek device has double thickness at each of its numerous bridge portions. Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1355 (Fed. Cir. 2003). Defendants could have asserted that these references make obvious the scope of equivalents Cordis asserted. They did not do so.

B. At Trial, AVE Chose Not to Raise an Obviousness Defense to the a Scope of Equivalents Asserted by Cordis

Despite an opportunity and incentive, AVE did not raise an obviousness challenge to the claim scope that Cordis asserted under the doctrine of equivalents.

C. At Trial BSC Raised and then Abandoning an Obviousness Challenge to the Scope of Equivalents Asserted By Cordis

At trial, BSC also had an incentive and opportunity to mount an obviousness attack on the claim scope that Cordis asserted under the doctrine of equivalents – a claim scope that is as broad as the claims' literal scope under the revised construction.

**1. BSC Raised an Obviousness Challenge
During the Liability Phase and then Abandoned It**

During the trial's liability phase, BSC raised – and then abandoned – an obviousness challenge to the claim scope that Cordis asserted under the doctrine of equivalents. BSC's counsel raised the issue at trial during cross-examination of Cordis' engineering expert, Dr. Collins, when he asked Dr. Collins if he had taken the prior art into account in his equivalents analysis, "so that you would limit the equivalents [under Wilson Sporting Goods] in a way that you would not end up covering what was in the prior art?" D.I. 198 at Tr. 1277:15-22. BSC's counsel then asked Dr. Collins to agree that Cordis would not be entitled to a scope of equivalents that covered prior art references such as Ersek:

Q. [I]s it your understanding that considering the question of equivalents, that the range of equivalents should be narrower than a range which covers prior-art patents like Ersek?

A. [C]ertainly I'd expect that I couldn't look to the prior art and find – find the equivalent. Otherwise, it wouldn't be patentable.

D.I. 199 at Tr. 1323:2-14. BSC's counsel continued to press the subject, and Dr. Collins repeatedly agreed that Cordis would not be entitled to a claim scope under the doctrine of equivalents that covered prior art references such as Ersek. See Section I(A)(2), supra.

The obvious aim of this cross-examination was to set the stage for testimony by BSC's experts that the claim scope Cordis asserted under the doctrine of equivalents was obvious in light of Ersek and other references. BSC's expert Dr. Cumberland had raised that issue in his expert report. But when BSC's experts testified, they carefully avoided the subject. And after raising the issue in opening statements and in cross-examining Dr. Collins, BSC chose not to mention it in closing argument. See Section I (A)(2), supra.

2. BSC Twice Stipulated to Forego an Obviousness Challenge with Respect to Damages

In order for Cordis to recover the "lost profits" damages it sought against BSC, Cordis needed to show that AVE's stents were not "non-infringing substitutes" for the NIR. To prove that AVE's stent infringed under the Court's earlier claim construction – i.e., to prove that they were not "non-infringing substitutes" – Cordis needed to rely on the doctrine of equivalents. See D.I. 462 (June 18, 2004 Order) at 20-21.

If BSC had been able to sustain an obviousness challenge to the scope of equivalents Cordis asserted against the AVE stents, it could reduced the \$324 million damage award by many millions of dollars. Yet BSC decided to forego that obviousness challenge. It entered into two separate stipulations to that effect.

The first stipulation was entered into prior to trial and addressed the accused products in the AVE case – the MicroStent II and GFX stents. D.I. 787 at 1; D.I. 788 at 3-4; D.I. 789 at 1; D.I. 205 at Tr. 2860:19-2861:6. The second stipulation was entered into during the trial's damages phase, and covered AVE's "S Series" stents. The "S Series" stents were not covered by the first stipulation; they were not accused products in the AVE case; and they were not the subject of a verdict by the AVE jury. D.I. 205 at Tr. 2836:6-18, 2863:9-14. In both stipulations, BSC agreed not to contest Cordis' allegation that AVE's stents – which could only infringe under the doctrine of equivalents under the Court's pre-trial rulings – were not "non-infringing substitutes" for the NIR.

D. Defendants' Waiver of an Obviousness Challenge to the Scope of Equivalents Asserted by Cordis Bars Them From Raising An Obviousness Challenges to that Claim Scope

By not raising an obviousness challenge to the scope of equivalents that Cordis asserted at trial, AVE waived an obviousness challenge to that claim scope. BSC waived an obviousness

challenge to that claim scope by raising an obviousness challenge and then abandoning it.

Neither defendant is entitled to a "second bite at the apple." USA Petroleum, 13 F.3d at 1280, 1282; NLRB v. Dole, 334 F.3d at 490; EEOC v. Westinghouse, 925 F.2d at 631. Because the scope of equivalents that Cordis asserted at trial is at least as broad as the claims' literal scope under the revised construction, defendants' waiver bars them from challenging the obviousness of the claims' literal scope under the revised construction. USA Petroleum, 13 F.3d at 1280, 1282; NLRB v. Dole, 334 F.3d at 490; EEOC v. Westinghouse, 925 F.2d at 631.

Moreover, the mandate rule "forecloses relitigation of all issues previously waived by the defendant[s]," Quintieri, 306 F.3d at 1225 – including an obviousness challenge to that claim scope. By their own waiver, defendants established the nonobviousness of that claim scope as the "law of the case." Magnesystems, 933 F. Supp. at 949-50. Under the mandate rule, they are not entitled to revisit the issue now. Id.; see also Abbott, 2003 WL 22462614 at *2.

III. HAVING LITIGATED THE OBVIOUSNESS OF THE '984 INVENTION AND LOST, AVE IS NOT ENTITLED TO RE-TRY THE ISSUE NOW

The same considerations, and others, apply to the Schatz '984 patent. (The '984 patent was asserted against AVE only, and not against BSC.).

A. This Court Did Not Authorize Post-trial Expert Reports on '984 Validity

The Court authorized the recent round of post-trial expert reports and expert discovery on validity in its May 14, 2004 Order. D.I. 1228. That Order included a section entitled "**Validity of the '762 patent**," id. at 3 (emphasis in original), which allowed "supplementation of the parties' expert reports on validity to address the new claim construction on the 'slots formed therein' and 'substantially uniform thickness' limitations." Id. At no time did the Court grant AVE leave to serve supplemental expert reports on the validity of the Schatz '984 patent.

Exhibit

AA

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)	
<i>Plaintiff,</i>)	
v.)	
MEDTRONIC AVE, INC., BOSTON)	C.A. No. 97-550-SLR
SCIENTIFIC CORPORATION and)	
SCIMED LIFE SYSTEMS, INC.,)	
<i>Defendants.</i>)	

MEDTRONIC AVE, INC.,)	
<i>Plaintiff,</i>)	
v.)	C.A. No. 97-700-SLR
CORDIS CORPORATION, et al.,)	
<i>Defendants.</i>)	

BOSTON SCIENTIFIC CORPORATION,)	
<i>Plaintiff,</i>)	
v.)	C.A. No. 98-19-SLR
ETHICON, INC., et al.,)	
<i>Defendants.</i>)	

**COMBINED REPLY BRIEF IN SUPPORT OF CORDIS'
MOTION FOR PARTIAL SUMMARY JUDGMENT
AGAINST AVE AND BSC ON '762 AND '984 OBVIOUSNESS**

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Dated: November 22, 2004
150405.1

2. BSC

BSC does not dispute that it had an opportunity and incentive to raise a Wilson Sporting Goods issue for the "substantially uniform thickness" limitation. Instead, BSC focuses on "slots formed therein." It argues (Br. at 15-16) that it had no incentive *in the liability phase* to show that the prior art rendered obvious the scope of equivalents for "slots formed therein." However, the liability phase was not the only phase of this case. BSC does not deny that it had an incentive to raise the issue *in the damages phase*, to reduce the damage award. See Cordis' Opening Br. at 22.

Despite that opportunity, BSC made a tactical decision not to raise the issue. It stipulated on two occasions not to raise it – once *before* the damages trial and again *during* the damages trial. The fact that BSC twice agreed *not* to raise the issue does not mean it had lacked an opportunity to do so. Instead, it waived any validity challenge.

Left with no real answer to its waiver, BSC asserts that "differences between a Wilson Sporting Goods analysis and a traditional validity challenge ... make Cordis' waiver theory inappropriate." BSC Br. at 19. BSC makes this argument by misreading a quote from Key Mfg. Group, Inc. v. Microdot, Inc., 925 F.2d 1444, 1449 (Fed. Cir. 1991), that Wilson Sporting Goods "'does not envision application of a full-blown patentability analysis.'" BSC Br. at 19. But, as Chisum makes clear, the aspects of a "full-blown patentability analysis" not envisioned by Wilson Sporting Goods are issues unrelated to obviousness, such as written description and enablement. 5A Donald S. Chisum, Chisum on Patents § 18.04[2][d][ii][D] (2004). Key confirms this in the passage immediately following the snippet BSC selectively quotes (id., 925 F.2d at 1449):

Wilson simply acknowledges that prior art limits the coverage available under the doctrine of equivalents. The question

under Wilson is whether the [asserted scope of equivalents] "could have been allowed by the PTO over the prior art."

Conroy v. Reebok Int'l Ltd., 14 F.3d 1570 (Fed. Cir. 1994), which BSC cites, confirms that a Wilson Sporting Goods analysis involves application of "standards of patentability consistent with our jurisprudence regarding anticipation and obviousness." Conroy, 14 F.3d at 1576-77.

*

*

*

AVE and BSC had an opportunity and incentive to show that the prior art renders obvious a claim scope that is co-extensive with the claims' literal scope under the revised construction. Having waived the issue at trial, they are in "no position" to resurrect it after an appeal. Westinghouse, 925 F.2d at 631.

C. The Court Has Not "Rejected" or "Implicitly Rejected" Cordis' Positions

Without quoting any portion of any Court order, defendants repeatedly state that this Court has "rejected" or "implicitly rejected" Cordis' arguments. E.g., BSC Br. at 1, 2, 14; AVE Br. at 3, 12-13, 23. Repeating this mantra does not make it correct.

AVE argues (Br. at 12-13, 23) that the Court "implicitly rejected" Cordis' arguments in its Order dated May 14, 2004, but it cannot point to anything in the Order to back up that assertion. In fact, the Order explicitly recognized that once expert discovery ends a case-dispositive motion may be "the most appropriate means to resolve this litigation." D.I. 1228 at 3. Cordis is now bringing the case-dispositive motion that the Order contemplates.

By e-mail dated May 26, 2004 (Exhibit 1 hereto), Cordis asked for clarification on the issue at hand – whether the Court had, in fact, denied Cordis' motion to reinstate the obviousness verdict. If the Court had denied Cordis' motion, it would have been easy to say so. But that was not the Court's response. In an email dated May 28, 2004, the Court responded that "Judge Robinson has reviewed your email and has these comments: Validity: The court obviously

Exhibit BB

1 - VOLUME I -
2 IN THE UNITED STATES DISTRICT COURT
3 IN AND FOR THE DISTRICT OF DELAWARE
4 CORDIS CORPORATION, : CIVIL ACTION
5 Plaintiff :
6 vs. :
7 MEDTRONIC AVE, INC., et al. : NO. 97-550 (SLR)
8 BOSTON SCIENTIFIC : CIVIL ACTION
9 CORPORATION, et al., :
10 Plaintiffs :
11 vs. :
12 ETHICON, INC., et al., : NO. 98-19 (SLR)
13 Defendants :
14 CORDIS CORPORATION, : CIVIL ACTION
15 Plaintiff :
16 vs. :
17 BOSTON SCIENTIFIC :
18 CORPORATION, et al., :
19 Defendants : NO. 98-197 (SLR)
20
21
22
23
24
25
Wilmington, Delaware
Wednesday, December 6, 2000
9:00 o'clock, a.m.

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury

Official Court Reporters

1
2 PROCEEDINGS
3
4 (Proceedings commenced at 9:00 a.m., and the
5 following occurred without the presence of the jury.)
6
7 THE COURT: I understand there is an issue.
8 MR. DISKANT: Yes, your Honor. The defendants
9 wish to play today the videotape deposition of Dr. Stanley
10 Carson. We do not object to that. Also, however, they
11 wish to introduce into evidence Dr. Stanley Carson's sworn
12 declaration.
13 That is classic hearsay. Dr. Carson was
14 examined. He was asked questions. He was cross-examined.
15 They had the opportunity to bring him here to Court live
16 if they wanted.
17 But a written witness statement does not
18 come into evidence, it doesn't go back to the jury so
19 they can read it. It is inadmissible. We object to it.
20 MR. BADENOCH: Your Honor, the problem is
21 this: Dr. Carson is, of course, not under our control.
22 He lives in California. Unlike a situation where we
23 were taking a -- if we had had an opportunity to examine
24 him on direct and they had cross-examined, which is not
25 the situation here -- what happened here is he filed a

1 APPEARANCES:
2
3 ASHBY & GEDDES
4 BY: STEPHEN J. BALICK, ESQ.
5
6 -and-
7
8 PATTERSON, BELNAP, WEBB & TYLER, LLP
9 BY: GREGORY L. DISKANT, ESQ.,
10 EUGENE M. GELERNTER, ESQ.,
11 WILLIAM F. CAVANAUGH, ESQ. and
12 MICHAEL J. TIMMONS, ESQ.
13 (New York, New York)
14
15 -and-
16
17 JOHNSON & JOHNSON
18 BY: ERIC I. HARRIS, ESQ.
19
20 Counsel for Plaintiffs
21
22 YOUNG, CONAWAY, STARGATT & TAYLOR
23 BY: JOSEY W. INGERSOLL, ESQ.
24
25 -and-
26
27 KENTON & KENYON
28 BY: GEORGE E. BADENOCH, ESQ.,
29 PAUL A. BONDOR, ESQ.,
30 ALBERT J. BRENEISEN, ESQ.,
31 MICHAEL ZACHARY, ESQ. and
32 ARTHUR GRAY, ESQ.
33 (Washington, D.C.)
34
35 Counsel for Defendants
36
37 -----

1 declaration in the Cook case. He was then fully cross-
2 examined on the declaration by counsel for ETP and
3 counsel for Cordis.
4 What we have done to create the video is to
5 collect from that -- from what is basically hostile
6 examination the most coherent testimony that we can.
7 In that testimony, there is clear references
8 to a paragraph of the declaration he is talking about.
9 And in order to make sense of what he is talking about,
10 the jury needs to see the text of what it is that he is
11 being cross-examined about by counsel for EGP and/or
12 Cordis.
13 The other thing is that, basically, -- so
14 for context, it is absolutely necessary. Because they
15 cross-examined, basically, the policy on hearsay is that
16 you don't allow hearsay because there is no chance to
17 confront and cross-examine the witness. That is not
18 true here.
19 What we have is kind of like the English
20 system or the system in many courts in this country where
21 you have direct testimony put in by a statement and then
22 you have live cross-examination.
23 The other thing is the dates. They are in
24 the part that they are going to play to attack Dr. Carson,
25 who is going to point out that he was paid for an

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1 THE COURT: I am going to take five minutes.
 2 And we will come back.
 3 (Short recess taken.)
 4 ---
 5 (Court resumed after the recess, and the
 6 following occurred without the presence of the jury.)
 7
 8 MR. DISKANT: Your Honor, before the jury
 9 comes in, I had a comment for a moment on the suggestion
 10 that there is any sandbagging going on here, because that
 11 concerns me greatly.
 12 We have tried this case efficiently. The
 13 examination of Dr. Fischell by Boston took 15 minutes.
 14 Our cross-examination took 30 minutes. It was,
 15 respectfully, I believe, directly responsive to the
 16 allegations that were intended to be raised by the direct.
 17 That has been a consistent pattern throughout this case.
 18 Boston has consistently examined witnesses for 50 percent
 19 more time than we have. I have no control over those
 20 choices. Those are the choices they have made. We have
 21 made the choices that we have made in order to present
 22 the case that we wanted to present, including a rebuttal
 23 case responding to their evidence.
 24 And we intend to continue to try the case
 25 efficiently. Boston is making its choices and we are

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1 making our choices. There is no intention to do anything
 2 other than to try the case that we set out to try within
 3 the time parameters that your Honor has suggested.
 4 THE COURT: I understand that. If you want
 5 to present this evidence in your rebuttal case you may.
 6 All I am saying is you cannot present it now.
 7 MR. DISKANT: Thank you, your Honor.
 8 THE COURT: Is this witness still on the
 9 stand?
 10 MR. GELERNTER: We don't have any further
 11 questions.
 12 MR. ZACHARY: I will have about two questions
 13 on redirect.
 14 THE COURT: Let's bring the jury in.
 15 (At this point the jury entered the courtroom
 16 and took their seats in the box.)
 17 THE COURT: Mr. Gelernter.
 18 MR. GELERNTER: Dr. Fischell, I don't have any
 19 further questions.
 20 THE COURT: Mr. Zachary.
 21 MR. ZACHARY: Thank you, your Honor.
 22 REDIRECT EXAMINATION
 23 BY MR. ZACHARY:
 24 Q. Dr. Fischell, do you still have Exhibit 5089 in
 25 front of you that Mr. Gelernter was asking you some

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1 questions about?
 2 A. Yes.
 3 Q. I just wanted to confirm, Dr. Fischell, the date
 4 on this document is January 24, 1996.
 5 A. On my copy it looks like January 25, 1996. If you
 6 could enlarge it..
 7 I see at the bottom, yes, January 24, 1996.
 8 Yes, sir.
 9 Q. Mr. Turnlund, the engineer at IsoStent, did this
 10 drawing on or about January 24, 1996?
 11 A. Yes. He did this drawing from what I believe was
 12 my sketch.
 13 Q. I have handed you a copy of the '370 patent, which
 14 is Exhibit 5001, plaintiff's exhibit, and also a copy of
 15 Defendant's Exhibit 11,308. And do you see that in the
 16 '370 patent, on the second page, you have a list of prior-
 17 art references that the Patent Office had received?
 18 A. Yes, I see the list.
 19 Q. In the upper right-hand corner, there is a
 20 reference to a patent issued to Pinchasik, the 373 patent?
 21 A. Yes, I see that.
 22 ---
 23
 24
 25

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1
 2 Q. And is Defendant's Exhibit 11,308 a copy of the patent
 3 to Pinchasik?
 4 A. It appears to be.
 5 MR. ZACHARY: Your Honor, I offer Defendant's
 6 Exhibit 11,308 in evidence.
 7 MR. GELERNTER: No objection.
 8 THE COURT: All right.
 9 *** (Defendant's Exhibit No. 11,308 was received
 10 into evidence.)
 11 BY MR. ZACHARY:
 12 Q. One further question, Dr. Fischell. You indicated
 13 during your testimony you met with Cordis' counsel prior
 14 to coming here today to testify?
 15 A. I met with Cordis' counsel over the last several
 16 years.
 17 Q. But in preparation for your testimony today, you
 18 did meet with Cordis' counsel; correct?
 19 A. Yes.
 20 MR. ZACHARY: Thank you. No further questions.
 21 MR. GELERNTER: No question your Honor.
 22 THE COURT: All right. You may step down, sir.
 23 Thank you very much.
 24 (Witness excused)
 25 ---

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1 MR. BADENOCH: Ladies and gentlemen, our
2 next witness is going to be presented on the videotape.
3 It's Dr. Stanley Carson, who will talk to you about what
4 he recalls about some of the early -- the first ideas of Dr.
5 Palmaz. And he is not here, so we're going to play it on
6 videotape.

7 Excuse me, Dr. Fischell.

8 There is a reference to a paragraph of an
9 affidavit. The affidavit will not be in evidence, so I'm
10 going to read the paragraph to you so you will know what
11 Dr. Carson is talking about on the video.

12 In the affidavit, Dr. Carson says at paragraph
13 6:

14 "In the course of performing this work, Dr.
15 Palmaz asked me if I had any idea how the restenosis
16 problem could be addressed so that vessels could be kept
17 open. I told him that I would create a permanently
18 expandable metal stent that could be inserted over an
19 angioplasty balloon and be delivered percutaneously to the
20 point of vessel blockage, thereby permitting the balloon
21 to be inflated so as to open up the vessel and thereafter
22 to be deflated and withdrawn, leaving the stent in place
23 in the vessel to keep it open on a hopefully permanent
24 basis. I explained my conception to Dr. Palmaz as a
25 children's Chinese finger puzzle with cross-hatched

1 you hear from Dr. Carson's testimony and then we'll play
2 our excerpts.

3 (Videotape played as follows.)

4 "Question: Would you state your name for the
5 record, please?

6 "Answer: Stanley Carson.

7 "Question: Where were you born, sir?

8 "Answer: I was born in Kendallville, Indiana.

9 "Question: Where do you live now?

10 "Answer: Now, I live in Los Alamitos,
11 California.

12 "Question: When were you born?

13 "Answer: Would you repeat that?

14 "Question: Date of birth. When were you born?

15 "Answer: 12/1/41.

16 "Question: Dr. Carson, I'm going to hand you
17 what I've marked as Exhibit 2, which is your affidavit with
18 the attachments to it.

19 "Sir, who drafted that affidavit?

20 "Answer: By drafts, you mean typed it out?

21 "Question: No, sir. I mean came up with the
22 words to original place in that affidavit.

23 "Answer: I came up with the words largely.

24 Of course, I had discussion with my attorney.

25 "Question: Who is your attorney?

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1 expandable members. I had to explain this concept to Dr.
2 Palmaz on more than one occasion, as he had never heard
3 of a Chinese finger puzzle before."

4 MR. DISKANT: What is going to happen now,
5 ladies and gentlemen, is Boston is going to play you
6 excerpts from Dr. Carson's deposition that was taken five
7 years ago and that they would like you to hear. And then
8 we will have an opportunity to play you some additional
9 excerpts that we think you might be interested in. And
10 just to keep all these facts in sequence, you should
11 understand the following dates:

12 On September 22, 1994, Cordis sued Cook,
13 another manufacturer of balloon expandable stents.

14 Four and a half months later, on February 6th,
15 1995, Cook signed an agreement with Dr. Stanley Carson,
16 purchasing his alleged intellectual property rights and
17 paying him \$50,000.

18 Four months later, on June 14, 1995, Dr.
19 Carson wrote and sworn to a declaration supporting his
20 claim to be a co-inventor with Dr. Palmaz after he had
21 signed the initial agreement with Cook and after he
22 received the \$50,000.

23 That's the declaration Mr. Badenoch just read
24 to you.

25 First, we'll hear what Boston would like to

1 "Answer: Aaron Kramer.

2 "Question: And are you paying Mr. Kramer's
3 fees?

4 "Answer: No, I'm not paying his fee directly.

5 "Question: Cook & Company is?

6 "Answer: Cook & Company is paying his fees
7 directly, I believe.

8 "Question: Now, in this affidavit, which is
9 Exhibit 2, true and correct? Is everything in there
10 stated true?

11 "Answer: To the best of my belief at this
12 time, yes.

13 "Question: Approximately how much did you
14 make from your practice in 1994?

15 "Answer: It's a pretty good year. I couldn't
16 give you the exact amount as our year ends in August. But
17 my -- and I pretty much let my wife take care of these
18 details, but it was a very, very busy year. And my guess
19 is that it will be in the in the neighborhood of between
20 two and four hundred thousand dollars in gross income in
21 the practice.

22 "Question: Now, let's step back for a second.

23 "You read the Patent '665, and you say that
24 made you feel that Dr. Palmaz committed fraud on you.
25 Why?

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1 "Answer: Yes. Inasmuch as I understand fraud
 2 that -- I need to clarify that.
 3 "I was upset when I read this, and I felt I
 4 had been misled.
 5 "Question: And why?
 6 "Answer: There's more than one item, and I
 7 may not take these in the order that they appear in this.
 8 "Question: Okay. Go ahead. If you can
 9 remember off the top of your head, go ahead and tell me.
 10 "Answer: There are drawings here, and the
 11 first drawing I recognize as being very similar to and
 12 very much akin to the one that I made, that I gave to Dr.
 13 Palmaz when I first proposed this idea.
 14 "Question: Are you referring --
 15 "Answer: That is referred to as 1-A and 1-B
 16 in this document.
 17 "Question: Okay. And --
 18 "Mr. Kramer: The record should reflect you're
 19 holding up the patent when you say this document, the '665
 20 patent.
 21 "Go ahead.
 22 "The witness: Yes, I think it's also labeled
 23 here at the top as patent.
 24 "Now, I would assume perhaps -- I may be all
 25 wrong -- but also for other reasons that the patent, if

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1 it existed -- and, you know, I didn't have any reason to
 2 question it being -- I don't think I thought about it.
 3 But Johnson & Johnson's putting money into the market,
 4 there's probably a patent.
 5 "I had worked with them long enough to know
 6 that they like to protect, as does everybody, their
 7 investments.
 8 "Now, I would have felt that the patent would
 9 revolve around a particular design, configuration,
 10 manufacturer and use of the Palmaz configuration, or
 11 Palmaz stent it's been referred to, which is a specific
 12 type of stent.
 13 "That's one item.
 14 "And so here is another drawing that I don't
 15 think is original with Dr. Palmaz, but it now appears in
 16 this patent and --
 17 "Question: Could you, for the record, say --
 18 when you said this -- another drawing --
 19 "Answer: Another drawing, Figure 1-A and 1-B.
 20 2-A and 2-B appears to be that of the Palmaz stent. The --
 21 that's a bit annoying. It was to me at the time.
 22 "The other thing is that -- another thing is --
 23 not just the other thing, but another thing is that, quite
 24 frankly, in reading this, it appears to me that what has
 25 been covered by this patent is delivering a stent on a

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1 balloon to a specific location.
 2 "And I don't feel now, to this day, that that
 3 was his original concept. I feel I presented that concept
 4 to him. And at the time that I did it, I spent a lot of
 5 time explaining the stent and the concept and didn't get
 6 any feeling that this is anything but unfamiliar territory
 7 to him at that time.
 8 "The other thing that's going on here is
 9 that -- I don't know whether these are page or paragraph
 10 numbers here, the numbers at the top.
 11 "Question: Are page numbers.
 12 "Answer: All right. I'm going to refer,
 13 then, to Page No. 4 on the document '665.
 14 "Mr. Kramer: Let me explain this. That's
 15 Page No. 4, Column 4.
 16 "And then if you want to look under Column 4
 17 where you see the numbers here, you can refer specifically
 18 to those numbers.
 19 "That would be Column 4, Line 10, for example,
 20 would be that line. That's the way you read these?
 21 "Answer: Four lines above Line 10 on Column 4
 22 in '665, it states that a further feature of the present
 23 invention is that a wire mesh tube may be utilized as the
 24 intraluminal graft, which is I don't believe how I
 25 visualized the Palmaz stent as being a wire mesh.

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1 "I feel that the wire mesh was one of the
 2 ideas that I had originally proposed to Palmaz and to
 3 Vascor.
 4 "And reading on Column 3, same line --
 5 "Mr. Kramer: Yes, yes.
 6 "Answer: Same lines. Okay. -- Line 25 and
 7 in that same paragraph down from that --
 8 "Mr. Kramer: You can read them into the
 9 record, if you wish.
 10 "The witness: Okay.
 11 "Answer: 'The present invention includes, an
 12 expandable, tubular shaped membrane -- member having first
 13 and second ends and a wall surface disposed between the
 14 first and second ends, the wall surface being formed by a
 15 plurality of intersecting elongate members' -- which to me
 16 appears to be a wire mesh.
 17 "And again, I was a bit shocked.
 18 "One other item comes to mind is the date.
 19 "Question: And what about that upset you?
 20 "Answer: Well, there was a reason that I
 21 signed this November 15th, 1985 document to Dr. Palmaz.
 22 And I have just been reminded of the date, because I had
 23 sought this down and given a copy to Brian Bates.
 24 "And at the time that I signed this was not
 25 for purposes of payment, per se. At least that's not why

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1 I was told I was signing this patent.
 2 "So I feel that if he were going to patent my
 3 ideas, that he should at least have told me.
 4 "Question: The proposal to -- that you refer
 5 to as the proposal to Hancock -- Vascor, tell me what that
 6 was like.
 7 "Answer: Well, it was a pretty basic proposal
 8 in that we felt we needed to, in discussions with Dave
 9 Lentz, outline why something was needed, what was being
 10 done now and what we were proposing.
 11 "Question: When you say 'we,' who's the
 12 other -- who's the 'we?'
 13 "Answer: In discussions with Dave Lentz, he
 14 felt they needed this to fund it. They were fairly
 15 unfamiliar with catheters and catheter work, that they
 16 were not -- that wasn't part of their -- apparently,
 17 their mission.
 18 "Question: But I thought you said we drafted
 19 something. Who drafted something?
 20 "Answer: I don't -- we thought is what I recall
 21 saying."

22 ---
 23
 24
 25

1 or the recurrence after dilatation or the unsuccessful
 2 dilatation when an artery rebounds and perhaps keep the
 3 artery open longer but, certainly, initially, give more
 4 successful result, was to put a stent at the time of the
 5 dilatation, and the stent would keep the artery open by
 6 its configuration, framework, support.
 7 "We spent a lot of time in the proposal, in
 8 our discussions between Dr. Palmaz, myself and Dr. Lentz
 9 as to what would be acceptable with them as a proposal,
 10 in deciding how much time in the proposal to give to the
 11 current state of the art and catheters being used and so
 12 on, because we felt we were presenting it to people that
 13 weren't right in the midst of doing CAT digitization and
 14 this sort of thing.
 15 "Then we went to describe -- to make a
 16 proposal in the last part of it after outlining the
 17 problem and the possible solution for the problem in a
 18 way that it could be done.
 19 "There's some drawings. Both of those
 20 drawings, I think, were in the proposal.
 21 "The drawings that I looked at earlier,
 22 they're on one sheet of paper. They were held up for
 23 the camera.
 24 "I don't think they're in that format, as I
 25 recall. They may be. But to show what it might look

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1
 2 "Question: Was there a written proposal given
 3 to Vascor?
 4 "Answer: Yes.
 5 "Question: Who drafted that proposal?
 6 "Answer: I drafted it, along with Dr. Palmaz.
 7 We both worked on it. We exchanged copies and came up with
 8 a final.
 9 "Question: What did it say?
 10 "Answer: Best of my recollection, it stated
 11 that arteries that are obstructed cause problems --
 12 "The Reporter: I am sorry.
 13 "The Witness: -- arteries that are obstructed
 14 cause problems in the human body and that one of the ways
 15 to open the arteries or to get necessary blood flow
 16 through the arteries was to dilate the artery.
 17 "One problem with the technique of dilating an
 18 artery is that some arteries couldn't be dilated to
 19 adequate size and that some arteries would rebound after
 20 dilatation, and thrombosis in some arteries or clot
 21 formations in some arteries would occur after dilatation.
 22 "Basically stated, what we felt between us,
 23 the current state of the art of balloon dilatation was
 24 the arteries.
 25 "And that in order to offset the dilatation

1 like.
 2 "This is just a proposal. We have had not
 3 made one. We wanted to show how it might be delivered.
 4 We wanted to show how it might be made -- not how, but
 5 what it might be made of because the people that I was
 6 working with at Vascor and Hancock, a lot of the research
 7 that has been done has been on materials that can be used
 8 and retained in the vascular system.
 9 "Question: I'm sorry. A lot of research who
 10 has done? That you have done or that they have done?
 11 "Answer: That I had done with them had been
 12 done on the use of different materials in the vascular
 13 system that would or would not be acceptable to be left
 14 in the vascular system.
 15 "Question: When was the proposal written?
 16 "Answer: Most of the proposal, I believe, was
 17 written in the early eighties. Early eighties.
 18 "Question: 1980?
 19 "Answer: Yes.
 20 "Question: Well, let me ask you something.
 21 Had you thought of this concept prior to Dr. Palmaz asking
 22 you the question that you talk about in Paragraph 6?
 23 "Answer: I thought of the idea of leaving
 24 something in the blood vessel, yes.
 25 "Question: Had you thought of the idea of --

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1 as it is described in Paragraph 6 of your affidavit, prior
 2 to that time.
 3 "Mr. Kramer: You mean the whole concept?
 4 "Mr. Chasoff: Yes, sir.
 5 "The Witness: Not the whole concept. And I
 6 didn't think of all of this at once. It was overnight.
 7 "Mr. Chasoff: Okay.
 8 "Question: When did you first start thinking
 9 of this concept?
 10 "Answer: Well, originally, it would be in late
 11 '79, maybe middle '79.
 12 "If you're relating it to the idea of just
 13 having some type of balloon staying in the artery, which
 14 was how I would picture it, you would open the balloon
 15 and -- isn't that -- it is a beautiful shape of the artery
 16 around the balloon, but it would be nice if we could just
 17 leave the balloon there. Some people say that kiddingly
 18 to each other, watching these things. Residents and so on.
 19 "Of course, that doesn't work, because there's
 20 no flow through the balloon, so we're not getting any
 21 blood flow.
 22 "Then he asked the question, and it occurred
 23 to me that we could put something on the balloon and leave
 24 it there.
 25 "Question: So my understanding is that when

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1 Dr. Palmaz asked you the question, that you --
 2 "Answer: Well --
 3 "Question: -- got the idea of leaving a
 4 permanent expandable metal stent in the artery?
 5 "Answer: I don't know if that's the first
 6 time, but on or about that time.
 7 "It had come on with respect, I think, to a
 8 particular collapse of one we just couldn't dilate at
 9 the time. I just refocused the thinking around this.
 10 "That's my answer.
 11 "Question: Can you remember who the
 12 particular patient was?
 13 "Answer: No, I don't.
 14 "Question: Do you remember what kind of
 15 problems you had or what the surgery was of or the
 16 procedure that was undergone when you had this problem --
 17 "Answer: I think --
 18 "Question -- that prompted you to think of
 19 this idea?
 20 "Answer: I believe this was a dilatation of
 21 an iliac artery and that we were either unsuccessful or
 22 that it had collapsed or that we originally got it a
 23 little bit, but it just wasn't adequate.
 24 "It didn't look as good as we'd like it to
 25 look.

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1 "Question: Who came up with the idea after
 2 you told Dr. Palmaz about this, as you claim in Paragraph
 3 6, of trying to follow through and do something with it.
 4 "Mr. Kramer: Objection as vague.
 5 "Question: If you can answer it, please go
 6 ahead.
 7 "Answer: It is been a lot of time explaining
 8 the conception, as I referred to it here, and also Chinese
 9 finger puzzles, as referred to in here, which is the same
 10 thing, I'll say, as Chinese handcuffs.
 11 "And I pointed out that I had some research
 12 projects going and that if we could come up with a
 13 proposal, that we might be able to, in effect, get this
 14 funded by the people I was already working with, at least
 15 get us some seed money which would be enough to initiate
 16 the study.
 17 "And I had requested -- I really had in mind
 18 the fact that Dr. Palmaz, being a role gist and being
 19 interested in balloon angioplasty and not having as many
 20 research duties and projects going as I already had, this
 21 would be a good research thing for him to do. And I think
 22 he felt the same way.
 23 "Question: Did you anticipate that there
 24 would be problems in bringing this -- making this device
 25 work answer?

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1 "Answer: I -- what I envisioned the main
 2 problem to be was to actually develop a particular device
 3 that could be implanted, the -- largely the manufacture,
 4 the construction of such device.
 5 "We already had balloons and sheaths and guide
 6 wires and angioplasty.
 7 "So I looked upon the manufacture and the
 8 construction of the device as being a problem, one for
 9 which some engineering help available from Vascor would
 10 be desirable.
 11 "Question: Did you anticipate the problems
 12 only being engineering problems?
 13 "Answer: Not necessarily.
 14 "But I felt that was one of the big, major
 15 problems to address at that time.
 16 "Question: Did you see the need -- did you
 17 recognize that there would need to be a great deal of
 18 medical studies and tests before it could be approved by
 19 the FDA?
 20 "Answer: I was aware the FDA required --
 21 would require a number of studies and tests, some of which
 22 we had already -- I had performed on other grafts for
 23 Vascor.
 24 "Question: And when you went to Vascor, was
 25 it your idea that you would walk away from -- that you

Exhibit CC

- VOLUME L -
 IN THE UNITED STATES DISTRICT COURT
 IN AND FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, : CIVIL ACTION
 Plaintiff :
 vs. :
 MEDTRONIC AVE, INC., et al. : NO. 97-550 (SLR)
 BOSTON SCIENTIFIC : CIVIL ACTION
 CORPORATION, et al., :
 Plaintiffs :
 vs. :
 ETHICON, INC., et al., :
 Defendants : NO. 98-19 (SLR)
 CORDIS CORPORATION, : CIVIL ACTION
 Plaintiff :
 vs. :
 BOSTON SCIENTIFIC :
 CORPORATION, et al., :
 Defendants : NO. 98-197 (SLR)

Wilmington, Delaware
 Monday, December 11, 2000
 9:00 o'clock, a.m.

 BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury

 Official Court Reporters

PROCEEDINGS

(Proceedings commenced at 9:00 o'clock a.m.,
 and the following occurred without the presence of the
 jury.)

(At this point the jury entered the courtroom
 and took their seats in the box.)

THE COURT: This is just a brief good morning.
 Hope you all had a good weekend. We will, I think, schedule
 lunch from 12:30 to 1:30, so if you have questions during
 that time, we are not necessarily going to be around our
 phone. So we get an hour off during the day. If we don't
 hear from you, I will send a friendly note in about 4:00
 o'clock to see where you stand, whether you want to adjourn
 at 4:30 or 5:00, or whether you want to deliberate later on.
 So we will keep in touch with you, at least in
 that regard. And obviously, if you have got questions, we
 will try to get back to you as soon as we can.

Thank you very much. Have a good day.

(At this point the jury then left the
 courtroom, and the following occurred without the
 presence of the jury.)

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1 APPEARANCES:

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-and-

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 T. CY WALKER, ESQ. and
 JOHN BATEMAN, ESQ.
 (Washington, D.C.)

Counsel for Defendants

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THE COURT: All right. I need an hour off, so
 12:30 to 1:30, theoretically, we will have off, unless
 they send us a question that we have to answer. Hopefully
 we will have that off. When we get questions, we will let
 you know. If we have any other news we will certainly
 give you a call. Hope we have one number per side.

MR. CAVANAUGH: Your Honor, being the eternal
 optimist that I am, there are issues relating to damages
 that we would have to talk about. I don't know if your
 Honor wants to set some time today to do that.

THE COURT: We can. I absolutely have to get
 something done this morning. I don't know how we are
 going to manage all of this. We can meet at 11:00.

MR. CAVANAUGH: That is fine.

MR. BADENOCH: Your Honor, I think that is
 probably fine. We have different attorneys who will be
 handling the damages phase.

MR. CAVANAUGH: I spoke to Mr. Colbert last
 night from Kenyon, who is handling damages for them. He
 said that was great with him.

But I will call and double-check.
 We will assume 11:00, your Honor.

THE COURT: All right. Thank you.
 (Court recessed at 9:02 a.m.)

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1
 2 (Proceedings resumed at 11:34 a.m.).
 3
 4 THE COURT: I guess the first thing we need to
 5 do is address timing, because by my calculations, at most,
 6 we have 24 hours left. I don't know whether you need
 7 those. I certainly would suggest you don't use them unless
 8 you need them. But that is all the time I can squeeze out
 9 of the day here.
 10 MR. CAVANAUGH: Your Honor, I think you had
 11 allocated eleven hours per side for damages. That should
 12 be fine.
 13 MR. COLBERT: I agree, except I thought it was
 14 11-1/2. A total of 23 hours.
 15 THE COURT: Given the fact that Boston used an
 16 extra hour in its liability case, I think eleven hours is
 17 more than sufficient. So that is eleven hours each. That
 18 means we will start at 9:00 again, which is different from
 19 our schedule, and have a half-hour for lunch.
 20 That is the only way I can squeeze the hours in,
 21 since we are only getting less than three in today.
 22 So that is that issue.
 23 Do you have something to say?
 24 MR. CAVANAUGH: Yes. We both have something
 25 to say. There are a couple of issues.

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1 One, why don't I just list the issues and you
 2 can decide how you want to take them in order.
 3 The first issue is whether pre-judgment
 4 interest should be tried to the jury or to your Honor. I
 5 have been in cases where judges have allowed it to go to
 6 the jury on an advisory basis. There is a dispute between
 7 the experts as to what the appropriate rate is to use. I
 8 tried a case in front of Judge Buchwalter in the Eastern
 9 District of Pennsylvania where it went to the jury, took
 10 it on an advisory basis.
 11 I leave it to your Honor.
 12 THE COURT: This jury has enough today. No.
 13 MR. CAVANAUGH: That is fine, your Honor.
 14 The second issue has to do with the AVE
 15 verdict. We do intend to tell this jury about the AVE
 16 verdict. That was how we structured these trials, so
 17 that there would be a finding that the AVE stents were
 18 not noninfringing alternatives.
 19 There is a related issue to that, that is the
 20 AVE S series, which your Honor will recall was not part
 21 of the last case. We intend to prove that those are also
 22 not noninfringing alternatives because they are virtually
 23 identical, certainly as to Claim 23 of the '762, as the
 24 GFX, GFX 2.
 25 So what we would propose to do in order to

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1 prove that in the damages phase is, the jury is told
 2 about the verdict, they understand through Mr. Collins
 3 the basis for the GFX infringement, and then we will,
 4 through a different witness, simply show pictures and
 5 describe the characteristics of the S series to
 6 demonstrate that they are not noninfringing alternatives.
 7 We don't need an expert to do that. We have
 8 Federal Circuit case law that says we don't need expert
 9 proof in order to establish infringement and we certainly
 10 don't need it to prove it on this damage issue.
 11 The next issue we have is --
 12 MR. COLBERT: Would you like to address them
 13 one at a time, your Honor?
 14 THE COURT: I would like to address them one at
 15 a time.
 16 MR. COLBERT: Your Honor, I can't imagine a
 17 reason for putting in the AVE case. It is extremely
 18 inflammatory and prejudicial.
 19 I have offered to counsel for Cordis a
 20 stipulation. We would stipulate that Boston Scientific
 21 will treat the GFX, GFX 2, the Micro Stents, the products
 22 that were accused in the first phase of this trial against
 23 AVE, as infringing products.
 24 We, frankly, don't think the S series stents
 25 belong in this case at all. The S series stents, there

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1 was no evidence with regard to the S series stents in the
 2 earlier case. They are not accused in this action. We
 3 have no expert report on it.
 4 The testimony and documents that are being
 5 proffered by Cordis to prove the S series stents infringe
 6 are sort of in the nature of generalized comments. The
 7 commercial documents are very much the same.
 8
 9 MR. COLBERT (Continuing): As Mr. Diskant is
 10 very careful during the liability phase of this case to
 11 point out detailed analyses of the commercial embodiments
 12 of the accused products in the patents and that there is
 13 no evidence, no proffered evidence in the case. We think
 14 it is so prejudicial and inflammatory, your Honor, we
 15 would, rather than have that verdict come in, we would
 16 rather stipulate the S-series stents as well are out, but
 17 we don't believe we should be required to do that.
 18 If we stipulate, your Honor, the GFX, GFX 2
 19 and MicroStents infringe, then they should be free to argue
 20 that they're the same, but they shouldn't be allowed to put
 21 the verdict in. We think that would be the appropriate
 22 thing to do, if the Court wants allow them to try to prove
 23 the S-series stents infringe.
 24 MR. CAVANAUGH: Your Honor, we simply stipulate
 25 the jury may be left with the impression that Boston had

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1 made decisions as to what does or does not infringe as to
2 the AVE stents. I think we're entitled to show that a
3 jury has found that the GFX 2 infringes Claim 23 of the
4 '762 patent and then we will demonstrate similarities
5 between the S series and the GFX 2. We don't require
6 expert testimony to do that. The pictures and the
7 dimensions speak for themselves.

8 THE COURT: Go back to the first thing you
9 said about -- you said something, Mr. Cavanaugh, about the
10 reason you need the verdict form as opposed to just a
11 stipulation that these are infringing products is because
12 Boston shouldn't be allowed, the jury might think Boston
13 bought something?

14 MR. CAVANAUGH: My concern is Boston will say
15 yes, we stipulate that the GFX 2 infringes, but we don't
16 stipulate that the S series infringes, leading the jury
17 to believe that somehow there are these differences
18 between the product and that Boston is picking and
19 choosing which infringe and which do not infringe.

20 That's not the case. These cases were
21 structured in such a way so that, when we got to the BSC
22 damages phase, the jury would know that the AVE stents
23 infringe. And when we get to the AVE damages phase, BSC,
24 they will know that the BSC NIR stent infringes. That's
25 the way we structured these cases, your Honor. And I

1 MR. COLBERT: Your Honor, if I may, just a
2 moment.

3 Mr. Cavanaugh is right, this case was
4 structured so when the AVE case was over, to quote Mr.
5 Cavanaugh, this jury would know that the AVE stents
6 infringe. Subsumed within that is they would know the
7 accused AVE stents infringed. We're willing to agree
8 to that.

9 Secondly, this is not just a damages trial.
10 The ACS stent infringement issue as a liability issue has
11 to be decided here. And this would be one of the most
12 inflammatory prejudicial things to have in front of the
13 jury when they're trying to decide whether or not the ACS
14 products also infringe.

15 THE COURT: I agree. And I still find this
16 utterly -- this is patent law -- if we have to have
17 basically many liability trials on the ACS trial and the
18 S series, then the last thing I'm going to do is let the
19 jury verdict in.

20 However you want to structure it, Cordis, aside
21 from the verdict, if you want me to instruct, whatever
22 language you want to use is fine, but we're not going to
23 let the AVE jury verdict in.

24 Now, with respect to the S series, I frankly
25 don't know what kind of evidence is needed. Apparently,

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1 think starting to talk about stipulations instead of what
2 actually happened is prejudicial to us.

3 MR. COLBERT: Your Honor, I could solve Mr.
4 Cavanaugh's problem.

5 Instead of saying there is a stipulation, if
6 you gave the jury a direction that those are infringed, for
7 example, I think the appropriate thing to do is just say
8 the parties agree. I don't understand Mr. Cavanaugh's
9 particular problem with that. I'm not going to argue
10 that there was any decisional process made. I'm not going
11 to present to the jury any argument that this was a
12 conscious decision, just that the parties stipulate.

13 Your Honor, rather than my saying it, your
14 Honor could say that the parties have agreed that those
15 infringe, or you could say the parties do not dispute
16 that those infringe. Either one of those should solve
17 his problem.

18 MR. CAVANAUGH: Your Honor, I frankly don't
19 see the prejudice to Boston. Another jury has found that
20 another company's stent infringed.

21 THE COURT: I have not done it this way, to
22 tell you the truth, but I can't imagine that it's
23 appropriate or necessary to show one jury a verdict form
24 from another jury. That just strikes me as absolutely
25 inappropriate.

1 we can't have a whole liability phase on these things, so
2 it's something less than that. And with eleven hours, I
3 can't imagine it would be very much at all.

4 MR. CAVANAUGH: It's actually very brief, your
5 Honor. It's probably combined half an hour of testimony,
6 because the products really are very similar. And the
7 jury will also be told there is a pending lawsuit against
8 the S series.

9 MR. CAVANAUGH: Your Honor, we could make
10 this simpler. If they don't have a basis to challenge the
11 S series, if they will simply stipulate that the S series
12 also infringes, it's a lot simpler case.

13 MR. COLBERT: Of course.

14 MR. CAVANAUGH: I don't even have to put in
15 that case because they have not identified any difference
16 between the GFX 2 and the S series that would give rise
17 to a noninfringement argument.

18 MR. COLBERT: I'm sure Mr. Cavanaugh would like
19 me to stipulate the NIR products infringe as well.

20 MR. CAVANAUGH: That is no longer necessary.

21 MR. COLBERT: In point of fact, your Honor, is
22 that Boston Scientific is not responsible for proving
23 whether or not the S series stents infringe. Cordis must
24 prove whether or not the S series is a noninfringing
25 alternative or not. We do not have to prove it's a

1 noninfringing alternative.

2 THE COURT: Then it's their burden. I guess
 3 if there is whatever case law you have that I can read in
 4 the next 45 minutes, that gives me some guidance as to
 5 what is appropriate evidence in this kind of proceeding,
 6 then that will be helpful. So that settles that.

7 MR. CAVANAUGH: Okay. Your Honor, I think
 8 what we would ask for is an instruction from your Honor
 9 that the AVE MicroStent 2, GFX 1, and GFX 2 have been
 10 found to infringe Claim 23 of the '762 patent.

11 MR. COLBERT: And your Honor, I think that that
 12 is just a way of having your Honor with a stipulation do
 13 what Cordis would like to do, which is have the fact of the
 14 verdict before the jury. I think what they should be told
 15 is there is no dispute here as to whether or not the GFX,
 16 GFX 2 and MicroStent products infringe and they will be
 17 treated as infringing parties for purposes of this case.

18 MR. CAVANAUGH: Your Honor, there has been a
 19 finding. This jury does know about the lawsuits. Mr.
 20 Croce testified about the lawsuits. I'm fine with not
 21 going into that there has been a jury verdict. That a
 22 jury was similar to them was here earlier in the month.
 23 If your Honor will instruct that there has been a finding,
 24 because that is the reality, your Honor, that is what
 25 occurred and that's why we structured these cases this

1 way.

2 They're also going to hear about the fact
 3 there was an ACS settlement. We can't go into the details
 4 of it. Given your Honor's in limine ruling, neither side
 5 can go into it, but that's a fact that the jury will know
 6 about. The jury knows that we filed lawsuits against
 7 three companies. They're going to -- they know what
 8 happened in this case. They're going to hear testimony
 9 about the ACS settlement and they should be told by your
 10 Honor that there has been a finding that they infringe.

11 There is nothing inflammatory about that.
 12 There is nothing prejudicial about that. That is a fact
 13 which we should be able to rely on. And I will not, if
 14 your Honor gives that instruction, I will not go into
 15 anything relating to how that finding occurred.

16 THE COURT: I agree. I don't know when it is
 17 you want me to say that, but I agree that that is not
 18 inflammatory. It is the truth. And I agree to give that.

19 MR. COLBERT: Your Honor, if I may say briefly.

20 As I understand what they have asked the Court
 21 to do is to instruct the jury there has been a verdict,
 22 not give the verdict to the jury, but to instruct the jury
 23 that there has been a verdict against those products which
 24 is precisely the same as giving them the verdict.

25 THE COURT: No.

1 MR. CAVANAUGH: Saying there is a finding is
 2 not the same as saying there is no disagreement.

3 THE COURT: Trust me, it's not the same as
 4 giving one jury another jury's verdict on everything in
 5 that case. It is a finding of that other jury.

6 MR. COLBERT: Your Honor, if that is your
 7 Honor's decision, then I would like to go back. I'd like
 8 to think a moment but, as I pointed out, we still think
 9 it's so inflammatory and prejudicial we may be more
 10 inclined to accept the stipulation we will treat the S
 11 series stents as noninfringing rather than risk that
 12 prejudice.

13 That is an offer that was made, and we may
 14 accept that to keep the fact of the verdict and the
 15 verdict itself away from the jury. And if you give me a
 16 few minutes, perhaps we will come back at the close of
 17 what we're doing right now. If that is the case, that
 18 should resolve the issue.

19 ---
 20
 21
 22
 23
 24
 25

1 THE COURT: All right. I have to say, I will
 2 never structure trials like this again. If the whole
 3 purpose of doing this and bringing the first poor jury back
 4 the second time was to avoid the truth, which is that they
 5 found infringement, then this whole exercise has been a
 6 waste. And I have learned all sorts of things.

7 I don't need to hear from anybody. You go
 8 ahead and discuss. You let me know what your decision is.
 9 Let's move on.

10 MR. COLBERT: We have a couple of other
 11 issues, your Honor. One of which is, there is a question
 12 about Government sales. Our expert, Dr. Bell, has
 13 excluded Government sales because, under 28 U.S.C. Section
 14 1498, it is very clear that sales to the United States
 15 Government or products made for the United States
 16 Government are not subject to a damage award in the United
 17 States District Court. The only remedy that exists for a
 18 patentee is to seek a claim in the U.S. Court of Claims
 19 against the Government.

20 In Re: McHooker, which involved double-luminal
 21 hemodialysis catheters, which is 831 F. Supp. 1354, 1393,
 22 expressly in that case excluded the Government's sales
 23 from the damage consideration in that case.

24 We think there is really no way that I can
 25

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1 MicroStent 2, GFX, and GFX 2 stents infringe Claim 23 of
2 the '762 patent.
3 THE COURT: I didn't think we did the
4 MicroStent 2.
5 MR. CAVANAUGH: We did the 2. We didn't do
6 the 1.
7 THE COURT: All right. Well, the first thing
8 you proposed, which is what I'm making my decision on, is
9 the AVE, the MicroStent 2, GFX and GFX 2 has been found to
10 infringe Claim 23 of the '762 patent.
11 MR. CAVANAUGH: That's what I thought I said.
12 Mr. Diskant wasn't sure.
13 THE COURT: Anything else? I don't know when
14 to say that, though. When is it that I'm supposed to say
15 this?
16 MR. CAVANAUGH: Your Honor, I think it should
17 be very early in the case. And I have no problem if it
18 was in the preliminary instruction.
19 MR. BADENOCH: Your Honor, if I can just make
20 one statement... Because I was involved in the part where
21 we discussed the phase of the trial that you referred to.
22 The reason for structuring the trial this way was not, not
23 so that we would tell the jury how something was found,
24 merely so we would know the answer whether it was
25 infringing or not.

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1 The reason we structured the trial this way was
2 now we know the answer. The AVE GFX stents infringe.
3 That's a reason to tell them that. It's not a reason to
4 tell them there is a finding as if it were either a verdict
5 or judicially sanctioned, merely that they now must treat
6 the AVE stents as infringing.
7 THE COURT: All right. Well, I'm not -- it
8 doesn't seem to fit anyplace in the preliminary instructions,
9 to tell you the truth.
10 MR. CAVANAUGH: That's fine, your Honor. We
11 would ask for it somewhat early in the case so that the
12 jury, because we are going to talk about the AVE stents
13 and the jury needs a context, and I'm going to reference
14 it in my opening statement. And what I would propose to
15 say is, you know, Judge Robinson will tell you there has
16 been a finding.
17 THE COURT: All right. And Boston Scientific
18 is still opposed to simply being -- letting Mr. Cavanaugh
19 state the parties agree that the MicroStent 2, so that
20 it's not coming from me kind of in a vacuum? Wouldn't
21 that be better for you if I made my ruling on that?
22 MR. COLBERT: I have no objection to saying
23 there is no dispute or an agreement, but I don't want Mr.
24 Cavanaugh to be talking about a decision or verdict of an
25 earlier case.

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1 THE COURT: All right. That's your decision,
2 so I will --
3 MR. COLBERT: But, your Honor, if I may, in
4 terms of the timing of this...
5 THE COURT: Yes.
6 MR. COLBERT: And I said we want to caucus for
7 a minute. But if we don't decide to accept the offer to
8 stipulate so that that fact of the verdict goes before the
9 jury, I would suggest that the time to do it would be, the
10 only time it should be done is at the end of the case, the
11 final instructions, rather than during the case.
12 MR. CAVANAUGH: Your Honor, the expert and
13 our Vice President who is going to talk about the S series,
14 their testimony would make no sense unless we have that
15 instruction. The jury is not going to understand why
16 we're not talking about that.
17 THE COURT: Well, I'll tell you what. You all,
18 Boston Scientific, gather your heads together and decide
19 what you are going to do. I'll think about the timing
20 and we'll get together five minutes before 1:30. All
21 right?
22 MR. CAVANAUGH: Thank you, your Honor.
23 (Luncheon recess taken at 12:20 p.m.)
24 ---
25

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1
2 AFTERNOON SESSION
3
4 (Proceedings resumed at 1:27 p.m., and the
5 following occurred without the presence of the jury.)
6
7 THE COURT: Is there anything we need to
8 discuss before the jury comes in?
9 MR. CAVANAUGH: No, your Honor. I think we
10 have arrived at an agreement on the S series. Boston
11 Scientific will agree that the GFX, GFX 2, and the S
12 series stents infringe Claim 23 of the '762 patent. As a
13 result, I will not make any reference to the jury verdict
14 or that there has been a finding of infringement.
15 THE COURT: Thank you very much. Let's bring
16 our jury in.
17 (At this point the jury entered the courtroom
18 and took their seats in the box.)
19 THE COURT: Members of the jury: Since you
20 have found Boston Scientific liable for infringement of at
21 least one of Cordis' patents, you must now determine the
22 amount of damages to which Cordis is entitled for Boston
23 Scientific's infringement.
24 Just as they presented evidence to you on
25 infringement and validity, Cordis and Boston Scientific

Exhibit DD

INTERNATIONAL INSTITUTE FOR CONFLICT PREVENTION & RESOLUTION

**Before an Arbitration Panel Convened by
Alternative Dispute Resolution in Technology Disputes**

**JOHNSON & JOHNSON, a New Jersey Corporation and
CORDIS CORPORATION, a Florida Corporation,**

Claimants

v.

**MEDTRONIC, INC., a Minnesota Corporation and
MEDTRONIC AVE, INC., a California Corporation,**

Respondents

AWARD OF ARBITRATORS

ISSUES TO BE DECIDED:

1. Do Johnson & Johnson and its Affiliates have a license under the Settlement and License Agreement dated November 4, 1997, as amended, to Medtronic Affiliate's patents owned by that Affiliate before November 4, 1997, even though Medtronic acquired that Affiliate after November 4, 1997?

Answer: No

If yes, do Medtronic, Inc. and its Affiliates enjoy the same benefit under the Settlement and License Agreement dated November 4, 1997, as amended? That is, do Medtronic and its Affiliates have a license under the License Agreement, as amended, to a Johnson & Johnson Affiliate's patents owned by that Affiliate before November 4, 1997, even if Johnson & Johnson acquired that Affiliate after that date?

Answer: Not applicable because of negative answer to preceding question.

AWARD OF ARBITRATORS – 2

2. Have J & J and its Affiliates granted Medtronic and its Affiliates a license under the Settlement and License Agreement dated November 4, 1997, as amended, to make, use, offer to sell, or sell the following accused products at issue in *Cordis Corp. v. Medtronic AVE, Inc.*, C.A. No. 00-886-SLR (D. Del. 2000)?

Answer:

S540 Coronary Stent Systems

Yes X (for Medtronic and its Affiliates) No ____ (for J&J and its Affiliates)

S670 Coronary Stent Systems

Yes X (for Medtronic and its Affiliates) No ____ (for J&J and its Affiliates)

S660 Coronary Stent Systems

Yes X (for Medtronic and its Affiliates) No ____ (for J&J and its Affiliates)

S7 Coronary Stent Systems

Yes X (for Medtronic and its Affiliates) No ____ (for J&J and its Affiliates)

Driver Coronary Stent Systems

Yes X (for Medtronic and its Affiliates) No ____ (for J&J and its Affiliates)

X3 Renal Stent Systems

Yes X (for Medtronic and its Affiliates) No ____ (for J&J and its Affiliates)

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AWARD OF ARBITRATORS - 3

3. Does the covenant not to sue in the Settlement and License Agreement dated November 4, 1997, as amended, bar J&J's and Cordis' claims that Medtronic AVE has infringed the Cordis patents in dispute in *Cordis Corp. v. Medtronic AVE, Inc.*, C.A. No. 00-886-SLR (D. Del. 2000)?

Answer: Yes X No

Date: February 20, 2006

By:



Hon. Susan S. Soussan

Date:

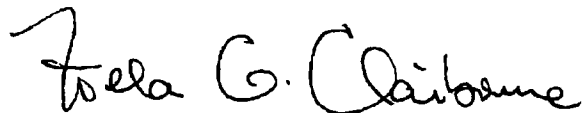
By:

David Plimpton, Esq.

Date:

By:

February 20, 2006



Zela G. Claiborne, Esq.

INTERNATIONAL INSTITUTE FOR CONFLICT PREVENTION & RESOLUTION

Before an Arbitration Panel Convened by
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JOHNSON & JOHNSON, a New Jersey Corporation and
CORDIS CORPORATION, a Florida Corporation,

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v.

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Respondents

DISSENT FROM
AWARD OF ARBITRATORS

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Answer: No

If yes, do Medtronic, Inc. and its Affiliates enjoy the same benefit under the Settlement and License Agreement dated November 4, 1997, as amended? That is, do Medtronic and its Affiliates have a license under the License Agreement, as amended, to a Johnson & Johnson Affiliate's patents owned by that Affiliate before November 4, 1997, even if Johnson & Johnson acquired that Affiliate after that date?

Answer: Not applicable because of negative answer to preceding question.

~~AWARD OF ARBITRATORS 2~~

DISSENT FROM
AWARD OF ARBITRATORS

2. Have J & J and its Affiliates granted Medtronic and its Affiliates a license under the Settlement and License Agreement dated November 4, 1997, as amended, to make, use, offer to sell, or sell the following accused products at issue in *Cordis Corp. v. Medtronic AVE, Inc.*, C.A. No. 00-886-SLR (D. Del. 2000)?

Answer:

S540 Coronary Stent Systems

Yes____(for Medtronic and its Affiliates) No X (for J&J and its Affiliates)

S670 Coronary Stent Systems

Yes____(for Medtronic and its Affiliates) No X (for J&J and its Affiliates)

S660 Coronary Stent Systems

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Yes____(for Medtronic and its Affiliates) No X (for J&J and its Affiliates)

(2)

~~AWARD OF ARBITRATORS~~

DISSENT FROM
AWARD OF ARBITRATORS

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Answer: Yes _____ No X

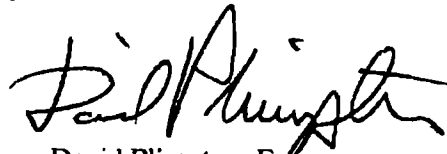
Date:

By:

Hon. Susan S. Soussan

Date: FEBRUARY 20, 2006

By:


David Plimpton, Esq.

Date:

By:

Zela G. Claiborne, Esq.

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